Company Introduction

510k imports, llc
510kimports.com
About Us

The Situation:

• In the US, we are faced with a shortage of Personal Protection Equipment (PPEs) during this Covid-19 pandemic;
• China is the largest supplier of PPEs in the world;
• But its a difficult (sometimes insurmountable) task for US companies and institutions to access reliable suppliers in China and ensure quality.

Our Mission:

• At 510 Imports, our goal is to deliver quality PPEs from reliable Chinese producers direct to companies and institutions in the US.

Our Qualifications:

• We are seasoned healthcare executives with a combined 100+ years of cross border experience in the healthcare industry
• Successful track record in regulatory, quality manufacturing, supply chain management/logistics, and cross border corporate strategies.
• Dedicated teams on the ground in US and China, with experience staff and affiliates united in accomplishing Our Mission.
Our Supplies and Service

Our Supplies:

• Direct contracts with reliable Chinese manufacturers of PPEs
• All manufacturers and products are screened to meet Chinese and US regulatory requirements

Quality Assurance:

• Our China team filter out and secure capacity with reliable PPEs manufacturers in China
• Our China team monitor the manufacturing and entire shipment process in China.
• Full SGS inspections before shipment
• Our goal is to ensure quality products, direct from manufacturer, are safely transported to the US

Our Service:

• Easy access to our customer service and executive team in the US
• Call us with any questions, whether its product inquiry, regulatory guidance, logistics coordination, or technical support.
Regulatory and Compliance Specialists

Managing and Supporting

• 510(k) Approvals
• EUA Approvals
• QSR – Quality System Regulations
• MDR – Medical Device Reporting
• Product Compliance Reviews – ISO, EN, UL, IEC, NFPA, NIOSH
• Initial Importer
• International Approvals - CE Marking, Notified Body, FDA
Product Compliance

- Validation
- Human Factors/Usability
- FDA Standards Testing
- Performance Ratings
- Supply Chain Audits
- Biocompatibility
- Risk Assessments
- Instructions for Use
# Import & Distribution Services

<table>
<thead>
<tr>
<th>Service</th>
</tr>
</thead>
<tbody>
<tr>
<td>Warehouse</td>
</tr>
<tr>
<td>Initial Importer</td>
</tr>
<tr>
<td>FDA Action/FDA Recall</td>
</tr>
<tr>
<td>Distribution</td>
</tr>
<tr>
<td>Installation and technical support</td>
</tr>
<tr>
<td>FDA Registrations</td>
</tr>
<tr>
<td>Commerce</td>
</tr>
<tr>
<td>MDR – Medical Device Reporting [21 CFR Part 803]</td>
</tr>
</tbody>
</table>
Team

Justin Heyl
Managing Director
- Over 35 years of medical compliance experience
- Notified Body
- 510(k) third party review
- Hospital procurement compliance programs
- Medical consulting
- UL llc, Intertek, Inchcape PLC
- Compliance program management
- Medical device design
- Global Accounts Managed
  - 3M
  - Medtronic
  - Philips
  - St. Jude

LaTatia Colbert-Reed
Marketing and Sales
- Over 30 years of Marketing, Sales and Market Analysis
- Strategic Planning
- Campaign Strategy Implementation
- Budget Management
- State Government and Federal Legislative Policy
- International Marketing
- Domestic and Global Marketing and Sales Roles
  - Bayer Healthcare - Biological Products
  - Talecris Biotherapeutics
  - Grifols, Inc.
  - Kedrion Biopharma
  - Purdue Pharma
Available Products

All Information is of May 28, 2020
Please note:

• **Payment Terms:** At such a time as any and all items or supplies ordered from 510k Imports to the State are received, inspected and have met the State’s approval, payment of rendered invoice for said items or supplies is due in full.

• **Logistics:** Due to the worldwide demand for masks, they are manufactured on an order-by-order basis. Standard Global Services (SGS) inspection for each shipment takes 2 to 3 days. Customs and airfreight can be 1 to 2 weeks, depending on availability of flights. Lead time from order to delivery is approximately 3 to 4 weeks. If there is any issue with any item ordered, the State will be notified ahead of time or upon receipt of order.

• **Country of Origin:** China (including Taiwan) and Thailand via Certified Manufacturers.
Test Kits

All Information is of May 28, 2020
# PRODUCT / PRICE SUMMARY – TEST KIT

<table>
<thead>
<tr>
<th>ORDER #’S</th>
<th>PRODUCT TYPE</th>
<th>CERTIFICATION /AUTHORIZATION</th>
<th>TEST/APPLIED STANDARD</th>
<th>MANUFACTURER</th>
<th>UNIT PRICE FOB (USD)</th>
<th>PACKING</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-1</td>
<td>GB SARS-CoV-2 Real-Time RT-PCR User Manual (nucleic test)</td>
<td>Class III IVD Taiwan GMP ISO 13485 Applying for EUA</td>
<td>Performance can be seen in “product info”</td>
<td>Taiwan</td>
<td>$10.70</td>
<td>100 test per kit Carton size: 48cm<em>32cm</em>64cm Carton weight: 21kg</td>
</tr>
<tr>
<td>1-2</td>
<td>Novel Coronavirus (2019-nCoV) RT-PCR Detection Kit (nucleic test)</td>
<td>NMPA EUA CE ISO13485:2016</td>
<td>Performance can be seen in “product info”</td>
<td>China mainland</td>
<td>$13.06</td>
<td>Have different packing methods</td>
</tr>
<tr>
<td>1-3</td>
<td>2019-nCoV IgG/IgM Detection kit (antibody test)</td>
<td>NMPA PEUA CE ISO13485:2016</td>
<td>Performance can be seen in “product info”</td>
<td>China mainland</td>
<td>$11.88</td>
<td>50 test per kit 12 kit per carton Carton size: 56cm<em>28cm</em>37cm Carton weight: 7.6kg</td>
</tr>
<tr>
<td>1-4</td>
<td>COVID-19 IgG/IgM Rapid test kit (colloidal gold)</td>
<td>NMPA PEUA CE Applying for EUA</td>
<td>Performance can be seen in “product info”</td>
<td>China mainland</td>
<td>$9.44</td>
<td>20 tests per kit, 50 kits per carton Carton size: 63.9cm<em>39.5cm</em>32.5cm Carton weight: 9.7kg</td>
</tr>
</tbody>
</table>
GB SARS-CoV-2- Real Time Nucleic Test (Item 1-1)

For in-vitro Qualitative Detection of 2019-Novel Coronavirus in Human Respiratory Specimens and Sera

INTENDED USE

The GB SARS-CoV-2 Real-Time RT-PCR is an in vitro nucleic acid amplification test (NAT) for the qualitative detection of novel coronavirus (SARS-CoV-2) in the respiratory tract specimens (i.e., sputum), serum or plasma, utilizing Reverse Transcriptase Polymerase Chain Reaction (RT-PCR) and TaqMan probe technology.
GB SARS-CoV-2- Real Time Nucleic Test (Items 1-1)

**PERFORMANCE**

- **Limit of Detection (LoD):** $1 \times 10^2$ copies/ml
- **All serial dilutions of in-vitro transcription RNA of the target gene can be detected.** (102, 104, 106, 108 copies/ml < 37 Ct)
- **Including IC (internal control) as an indicator of the RT-PCR performance, which can reduce the results of false-negative.**

![Graphs of ORF1ab, E, and N genes](image-url)
Each kit provides reagents sufficient for performing 100 tests and consists of the following:

1. GB one-step Real-time RT-PCR reagent
2. Ready-to-use primer and probe mixture for E gene, N gene and ORF1ab region/E gene, ORF1ab region of SARS-CoV-2.
3. Nuclease-free water
4. Positive Controls
Company Profile

Who we are

General Biologicals Corporation (GBC), founded in 1984, is a developer and manufacturer of diagnostics and pharmaceutical. We develop high quality in-vitro diagnostics for doctors to make clinical decisions in the area of hepatitis, tumor markers, retro virus, fertility, Thyroid, and Steroids.

In general consumable applications, we provide an anti-bacterial peptide in areas of pharmaceutical, cosmetics, and oral products.

Our Value

- **Integrity**
  
  We are always honest and open to any feedback or comments we receive to maintain the highest quality of work. Most importantly, we care any unethical issues that may impact the sociality.

- **Intelligence**
  
  We strive the best to achieve customers’ goals as well as reaching corporate objectives set by ourselves.

- **Integration**
  
  We integrate our different talents and resources to provide the better experience for our customers to use our products and service.

- **Innovation**
  
  We continue to innovate from products to services with our partners and with our customers.
Novel Coronavirus (2019-nCoV) Detection Kit (nucleic test) (Item 1-2)

Features

- **Comprehensive**: 3 targets (ORF1ab, N and E genes) detected in 1 tube
- **Reliable**: Internal control, UNG enzyme and dUTP were used to reduce risk of contamination and false negative results
- **Faster results**: 1.5 hours post-extraction turnaround time
- **Sample Type**: Nasopharyngeal swab/Throat swab/Sputum/Stool
- **Instrument**: Four-channel RT-PCR instrument (FAM/JOE/ROX/CYS)

Product information

- **Registration certificate**: CE: Ref. No.: GZ 8821-2020 China NMPA: GUOXIE2HUZHUN 20203400299
- **Specification**: 48 tests/kit; 96 tests/kit
- **Sample type**: Nasopharyngeal swab/Throat swab/Sputum/Stool
- **Sensitivity**: 300 copies/mL
- **Amplification time**: 1h20min
- **Instrument**: Four-channel RT-PCR instrument (FAM/JOE/ROX/CYS)
- **Storage & Shelf Life**: -25°C ~ -15°C, 12 months
Novel Coronavirus (2019-nCoV) Detection Kit (nucleic test) (Item 1-2)

Main Components

<table>
<thead>
<tr>
<th>Component Name</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td>2019-nCoV Reaction Buffer</td>
<td>Deoxyribonucleotide, magnesium chloride, 2019-nCoV ORF1ab, E, N gene primer, fluorescence probe</td>
</tr>
<tr>
<td>RT-PCR Enzyme Mix</td>
<td>Taq DNA polymerase, reverse transcriptase, UNG enzyme</td>
</tr>
<tr>
<td>2019-nCoV Positive Control</td>
<td>Nucleic acid templates</td>
</tr>
<tr>
<td>2019-nCoV Negative Control</td>
<td>Normal saline</td>
</tr>
<tr>
<td>Internal control A</td>
<td>Nucleic acid templates</td>
</tr>
</tbody>
</table>

**Note**: The components in different batches of kits cannot be interchanged, and the freeze-thaw times shall not exceed 5 times.
2019-nCoV Results Interpretation (Item 1-2)

<table>
<thead>
<tr>
<th>Test Result</th>
<th>Results Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>OrF1ab gene, N gene and E gene have two or more (+)</td>
<td>2019-nCoV (+)</td>
</tr>
<tr>
<td>Only ORF1ab gene (+)</td>
<td>If repeat amplification is still positive, 2019-nCoV (+)</td>
</tr>
<tr>
<td>Only N gene or E gene (+)</td>
<td>2019-nCoV (-)</td>
</tr>
<tr>
<td>ORF1ab gene, N gene and E gene are all (-)</td>
<td>2019-nCoV (-)</td>
</tr>
</tbody>
</table>
Certifications – FDA, EUA authorized, NMPA approval and CE (Item 1-2)

PEOPLE'S REPUBLIC OF CHINA

REGISTRATION CERTIFICATE FOR MEDICAL DEVICE (IVD REAGENT)

Registration Certificate No.: GB/2020/255/2020/000024

Registration Name: Shanghai Fusi Long March Medical Science Co., Ltd

Address: No.1 Chenguang Road, Baidian District, Shanghai

Device: Nucleic Acid Detection Kit-RT-PCR Detection Kit

Compositions of Product:
2019-nCoV nucleic acid extraction solution, RT-PCR reagent, positive control solution of 2019-nCoV, negative control, internal reference A.

Intended Use:
The kit is intended for qualitative detection of 2019-nCoV in nasal swab, pharyngeal swab, sputum, stool samples from clinical suspected cases and asymptomatic cases of patients with suspected infection.

Appendix:

Storage & Shelf Life:
All reagents should be stored at -18°C to -25°C with protection from light, and the reagents are stable for 6 months when stored at the recommended condition.

Other:
The following work should be completed after being issued:

1. The product is the diagnostic instrument and emergency source of novel coronavirus (2019-nCoV) nucleic acid detection kit, and the application reports for medical device registration should be submitted to the registration authority in accordance with the requirements of diagnostic instrument registration method when continuing registration.

Grade: A

English Translated Version

ISO 13485

Certificate

Certificate No.: 2020-00017

Certificate Name: Shanghai Fusi Long March Medical Science Co., Ltd

Address: No.1 Chenguang Road, Baidian District, Shanghai

Grade: A

Certificate Mark:

EUA, NMPA approval and CE
Established in 1994, Shanghai Fosun Pharmaceutical (Group) Co., Ltd. ("Fosun Pharma"; stock code: 600196.SH, 02196.HK) is a leading healthcare group in the PRC. Adhering to the mission of improving human health, Fosun Pharma’s business covers all key sectors of healthcare industry chain, including pharmaceutical manufacturing and R&D, healthcare services, medical devices and medical diagnosis, as well as pharmaceutical distribution and retail, with pharmaceutical manufacturing and R&D as the core, and healthcare services as the development focus.

Fosun Pharma regards innovation, research and development as the core driving factor of development and has developed international R&D team in China, the United States, India and etc., and established innovative chemical drugs platform, biologics platform, high-value generic drugs platform and cell-therapy platform. Currently, Fosun Pharma continues to focus on therapeutic areas including oncology, cardiovascular system, central nervous system, blood system, metabolism and alimentary system and anti-infection. All major products occupy the leading position and maintained fast growth in each market segment.

In healthcare service segment, Fosun Pharma Group has strategically layout high-end medical in developed coastal cities, specialized and general hospital in second and third-tier cities. In 2018, the combined number of authorized beds controlled by Fosun Pharma including Chancheng Hospital, Hengsheng Hospital, Zhongwu Hospital, Wenzhou Geriatrics Hospital, Guangji Hospital, Jimin Cancer Hospital, Zhuhai Chancheng and Wuhan Jihe Hospital, etc. was 4,118 in aggregate. United family hospital, the affiliated hospital of Fosun Pharma Group, continues to maintain its leading position in premium healthcare in Beijing, Tianjin, Shanghai and other metropolitan in China.
2019-nCoV IgG/IgM Detection Kit (antibody test) (Item 1-3)

IgM and IgG Antibodies

Both IgM and IgG are immunoglobulin which are produced by the immune system to provide protection against the 2019-nCoV. Some patients with negative results in nucleic acid test show positive in IgM test, indicating that the IgG/ IgM detection is one of the effective methods for the diagnosis of 2019-nCoV.

Advantages of IgG / IgM Detection

01 Indicating both recent infections and previous infections, reducing missed detection rates.

02 Low requirements of instruments; suitable for primary hospitals and conventional outpatient clinics.

03 Blood testing; low requirements for sampling; no special virus collection tube required.

04 Suitable for combined detection with nucleic-acid testing kit to improve the diagnosis rate of suspected patients.
2019-nCoV IgG/IgM Detection Kit (antibody test) (Item 1-3)

**Product Advantages**

01. Rapid-screening within 10 minutes.
02. High detection efficiency: simultaneous monitoring of IgM and IgG.
03. Detection without any equipments.
04. Easy to operate, and is compatible with serum/whole blood/plasma.
05. Room-temperature storage.

**Product Information**

<table>
<thead>
<tr>
<th>Product Name</th>
<th>2019-nCoV IgG/ IgM Detection Kit (Colloidal Gold-Based)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Size</td>
<td>50 Tests/ Kit</td>
</tr>
<tr>
<td>Specimen</td>
<td>Serum / Plasma / Whole Blood</td>
</tr>
<tr>
<td>Required Volume of Specimen</td>
<td>20 µl</td>
</tr>
<tr>
<td>Storage</td>
<td>4°C - 30°C. Sealed.</td>
</tr>
</tbody>
</table>
2019-nCoV IgG/IgM Detection Kit (antibody test) (Item 1-3)

**Workflow**

For Whole blood / serum / plasma samples, please use the provided dropper to add 1 drop of sample (about 20 µL) to the sample loading position.

Add 2–3 drops of dilution buffer (about 60 µL) to the sample loading position.

**Results**

<table>
<thead>
<tr>
<th>Results</th>
<th>Interpreting</th>
</tr>
</thead>
<tbody>
<tr>
<td>IgM positive, IgG positive</td>
<td>Indicates that it may be a recent infection with 2019-nCoV.</td>
</tr>
<tr>
<td>IgM positive, IgG negative</td>
<td>Indicates that it may be a recent infection with 2019-nCoV.</td>
</tr>
<tr>
<td>IgM negative, IgG positive</td>
<td>Indicates that it may be a previous infection with 2019-nCoV.</td>
</tr>
<tr>
<td>IgM negative, IgG negative</td>
<td>Indicates that it may be on infection with 2019-nCoV, or there is not enough detectable antibodies in the early infection.</td>
</tr>
</tbody>
</table>
Product Information and Clinical Test Report (Item 1-3)

2019-nCOV IgG/IgM Detection Kit

**Product Information**

**Product Name**
2019-nCOV IgG/IgM Detection Kit (Colloidal Gold-Based)

**Main Characters of Product**
- Test Time: 10 min;
- Sample volume: 20μL;
- Specimen: serum, plasma, whole blood;

**Package**

<table>
<thead>
<tr>
<th>Quantity</th>
<th>Box Size</th>
<th>Package Size</th>
<th>Net Weight</th>
<th>Gross Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>50</td>
<td>175×130×140 mm</td>
<td>450×405×310 mm</td>
<td>7.8 Kg</td>
<td>8.8 Kg</td>
</tr>
</tbody>
</table>

**Storage Condition**
4-30°C

**Shelf Life**
18 Month

**Production Capacity**
300k Test per day

**Max Batch Size**
100 Million Test

**Clinical Test Report**

**Clinical Validation Method**
The test results of 2019-Novel Coronavirus (2019-nCoV) IgG / IgM Detection Kit (Colloidal Gold-Based) were compared with the diagnosis results (based on nucleic acid detection method) obtained by the above clinical trial organization. Then, the positive rate, negative rate, total coincidence rates and Kappa were analyzed.

**Analysis of Clinical Data**

<table>
<thead>
<tr>
<th>Sample Type</th>
<th>Clinical Diagnosis (n = 570)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum, Plasma and Whole Blood Samples</td>
<td>Positive</td>
</tr>
<tr>
<td>2019-Novel Coronavirus (2019-nCoV) IgG / IgM Detection Kit</td>
<td>184</td>
</tr>
<tr>
<td></td>
<td>17</td>
</tr>
</tbody>
</table>

**Conclusion**
The test results show that the Vazyme 2019-Novel Coronavirus (2019-nCoV) IgG / IgM Detection Kit has a high specificity and is one of the effective methods for the diagnosis of 2019-nCoV.

**Report Provided by**
Nanjing Vazyme Medical Technology Co., LTD.

**Date**
March 5th, 2020
Certifications – FDA, PEUA, NMPA approval and CE (Item 1-3)
Vazyme Biotech is devoted to the development and production of enzymes and antibodies. Our products cover clinical diagnosis, molecular diagnostics, high-throughput sequencing and life science research and other related fields. The company is located in the city of Nanjing, China’s ancient capital of the Six Dynasties. Vazyme Biotech is in the front of scenic Qixia mountain, dependent on the regional radiation force of the National Economic and Technological Development Zone of Nanjing. With advanced capability of R&D and cutting-edge technology, Vazyme Biotech will create a new pattern of National Biotechnology.

With a forward-looking vision and requirements of the international leading technology, Vazyme Biotech spent huge sums to build 8000 square meter of R&D site and 4000 square meter of the aseptic purification production workshop of IVD beyond the GMP standards. At the same time, the company also established marketing centers in the first-tier cities such as Beijing, Shanghai and Guangzhou and set up sales network around the whole country.

The level of R & D has highlighted the strength of Vazyme Biotech. Our technical team is comprised of scientists who are involved in the field of molecular biology, enzyme, immunology and bioinformatics. Many of them had been doing research and development work in the well-known international pharmaceutical companies and own a very mature industry experience.
COVID-19 IgG/IgM Rapid Test Kit (Colloidal Gold) (Item 1-4)

Introduction

IgM is the anti-body earliest comes into being in the primary humoral immune response. It is the vanguard against anti-infection. The detection of IgM in serum indicates a new infection.

Therefore it can serve for the early diagnosis of COVID-19. IgM accounts for 5%-10% of the total serum immunoglobulin, it is easier to detect and of high sensitivity. IgG antibody can be detected within several days after the invasion of illness and is the component of serum, accounting for 75% of serum immunoglobulin. Therefore IgM and IgG are of important clinical significance for the detection of COVID-19. IgM-IgG rapid test kit based on colloidal gold immuno-chromatography for COVID-19 can be easily used, highly sensitive, specificity-oriented and effective within a short period of time; which is particularly suitable for the detection of the infection of COVID-19.
COVID-19 IgG/IgM Rapid Test Kit (Colloidal Gold) 
(Item 1-4)

**Intended Use**

This product is used for in vitro qualitative detection of 2019-ncov (COVID-19) IgG/IgM antibodies in human whole blood, plasma and serum samples. This product is suitable for the auxiliary diagnosis of 2019-ncov (COVID-19) infection. 2019-ncov (COVID-19), mainly transmitted by inhalation and direct contact, is one of the main pathogens causing upper respiratory tract infection and lung diseases. It can cause the changes of the extrapulmonary system, which has aroused great concern. Timely and effective laboratory diagnosis of 2019-ncov (COVID-19) infection becomes particularly important.

This reagent uses immunochromatographic colloidal gold technique to detect 2019-ncov (COVID-19) IgG/IgM antibodies in samples. The detection card contains:

1) Recombinant COVID Antigen labeled colloidal gold.
2) Cellulose Membrane fixed with three lines (G line and M line) and one quality control line (C line). The M line was coated with mouse anti-human IgM antibody for detection of 2019-ncov (COVID-19) IgM antibody. The G line was coated with mouse anti-human IgG antibody for detection of 2019-ncov (COVID-19) IgM antibody. The C line was coated with sheep anti-chicken antibody. When specimen is added to sample well, capillary effect causes the fluid to flow to the NC membrane, COVID IgM (if present) will bind with mouse anti-human IgM and the M line will be visible. COVID IgG (if present) will bind with mouse anti-human IgG and the G line will be visible. No matter whether the specimen is positive or negative, the C line should be visible, otherwise the test is invalid.
COVID-19 IgG/IgM Rapid Test Kit (Colloidal Gold) (Item 1-4)

Components and Test Procedure

<table>
<thead>
<tr>
<th>COMPONENT</th>
<th>20 Test Kit/Box</th>
<th>40 Test Kit/Box</th>
<th>Main components</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test Kit</td>
<td>20 Test Kit Box (1 Test Bag ×20 Bags)</td>
<td>40 Test Kit Box (1 Test Bag ×40 Bags)</td>
<td>The detection lines were coated with mouse anti-human IgM antibody and mouse anti-human IgG antibody, the quality control lines were coated with sheep anti-chicken antibody, and the colloidal gold pad contained recombinant COVID Antigen labeled colloidal gold.</td>
</tr>
<tr>
<td>Dryer</td>
<td>20 Bags</td>
<td>40 Bags</td>
<td>Silica Gel</td>
</tr>
<tr>
<td>Specimen Diluent</td>
<td>1 Bottle (5mL)</td>
<td>1 Bottle (8mL)</td>
<td>Solution of trimethylaminomethane hydrochloride (0.02M Tris-HCl)</td>
</tr>
</tbody>
</table>

2. Plasma and serum: Collect the specimen with a pipette. Add 10μl plasma and serum into sample well. Add 2 drops diluent into sample well. Whole blood: Collect the specimen with a pipette. Add 20μl whole blood into sample well. Add 1-2drop diluent into sample well.
3. Start timing: The result should be read at 15-20 minutes. The result is invalid after 20 minutes.
Acknowledgment Letter

5/14/2020

From Wang

Acorna Integrated Inc.
1001 E Pender Street
Vancouver, BC V6A 1W1

Dear [Name]

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the unique document control number below. All future correspondence regarding this submission should be identified prominently with the number assigned and should be submitted to the Document Control Center at the above address. Failure to do so may result in processing delays. If you believe the information identified below is incorrect, please contact CDRH Operations Staff at (301) 796-5640.

Submission Number: EUA201008
Received: 5/14/2020
Applicant: [Company Name]
Device: [Device Name]

We will notify you when the review of this document has been completed or if any additional information is required. If you are submitting new information about a submission for which we have already made a final decision, please note that your submission will not be re-opened.

For information about CDRH review regulations and policies, please visit
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm

Sincerely yours,

Center for Devices and Radiological Health
JoysBio (Tianjin) Biotechnology Co., Ltd. is a Chinese R&D-based biotechnology company that develops, manufactures, and supplies high-quality medical in-vitro diagnostic (IVD) rapid test kits as well as revolutionary customized solution kits to all parts of the world. Founded by a team of professionals with many years of combined technical, marketing/sales, operational and manufacturing expertise in this industry, we offer high quality but cost-effective rapid test kit. Our in vitro diagnostic products screen for a wide range of targets, including infectious diseases, tumors, cardiac abnormalities, drug abuse and fertility. Our focus is to expand our markets internationally by forming strategic alliances and entering into partnerships with distributors worldwide.

JoysBio has established a comprehensive Quality Management System that is an applicable international standard (EN ISO 13485), ensuring top quality test results and accuracy. Also, our products are CE and CFDA certified.

Contact information:
Joysbio Biotechnology(Tianjin) Co., Ltd.
Add:Tianjin International Joint Academy of Biotechnology &Medicine
9th floor No.220, Dongting Road, TEDA,Tianjin, 300457 P.R.China

Tel:0086-022-65378415  65378699
Email:info@joysbio.com
Masks

All Information is of May 28, 2020
# PRODUCT / PRICE SUMMARY - MASK

<table>
<thead>
<tr>
<th>ORDER #S</th>
<th>PRODUCT TYPE</th>
<th>CERTIFICATION /AUTHORIZATION</th>
<th>TEST/APPLIED STANDARD</th>
<th>MANUFACTURER</th>
<th>UNIT PRICE FOB (USD)</th>
<th>PACKING</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-1</td>
<td>N95 Medical grade protection Sterilized with epoxy ethane</td>
<td>NMPA FDA</td>
<td>GB19083-2010 FDA class I FDA code: LYU</td>
<td>China mainland</td>
<td>$5.50</td>
<td>10pcs per box 96boxes per carton Carton Size:51cm<em>42.5cm</em>46cm</td>
</tr>
<tr>
<td>2-2</td>
<td>N95 general protection</td>
<td>NIOSH CE</td>
<td>TC-84A-8109 NO. RIZSQ1005b EN ISO: 13485:2016 CE Class I</td>
<td>China mainland</td>
<td>$6.05</td>
<td>20pcs per box 20boxes per carton Carton Size:69cm<em>40cm</em>34cm</td>
</tr>
<tr>
<td>2-3</td>
<td>KN95 Protective Mask Ear Loop Style</td>
<td>CE FDA EUA</td>
<td>GB2626-2006 Program Code: DEV Processing Code: NED Intended Use Code: 940.000</td>
<td>China mainland</td>
<td>$2.65</td>
<td>1000pcs per carton (10x100 packs) Carton size: 68cm<em>36cm</em>36.5cm</td>
</tr>
<tr>
<td>2-4</td>
<td>Taiwan made mask equivalent to N95 general protection S for children M for female L for male</td>
<td>GRS Oeko-Tex® Standard-100 MSDS US Nelson Japan Kaken ISO 9001 ISO14001</td>
<td></td>
<td>Taiwan</td>
<td>$1.00</td>
<td>3600pcs per carton Carton size: 50cm<em>56cm</em>48cm</td>
</tr>
</tbody>
</table>
N95 Medical Grade Protection Mask (Item 2-1)
NIOSH N95 General Protection Mask (Item 2-2)
NIOSH N95 General Protection Mask (Item 2-2)

1. Cup the respirator in your hand with the nosepiece at fingertips, allowing the head straps to hang freely below hand.
2. Position the respirator under your chin with the nosepiece up.
3. While holding the respirator in place, pull the top strap over your head so it rests high on the back of your head.
4. While continuing to hold the respirator firmly in place, pull the bottom strap over your head and position it around your neck, below your ears. Untwist the straps. Position the respirator low on your nose.
5. Using both hands, mold the nosepiece to the shape of your nose by pushing inward while moving your fingertips down both sides of the nosepiece. Note: Always use two hands when molding nosepiece. Pinching with one hand may result in improper fit and less effective respirator performance.

http://ia800204.us.archive.org/20/items/ParticulateFilteringFacepieceRespiratorUserInstructions/Rizhao8109.pdf
Certification - NIOSH N95 General Protection Mask (Item 2-2)
KN95 Protective Mask – Ear Loop Style (Item 2-3)
KN95 Protective Mask – Packing (Item 2-3)
## KN95 Protective Mask – Authorization (Item 2-3)

The Authorized Respirators

Authorized respirators should be used in accordance with CDC's recommendations. For the most current CDC recommendations on optimizing respirator use, please visit CDC's website: [Strategies for Optimizing the Supply of N95 Respirators](https://www.cdc.gov/niosh/maskstrategies/index.html).

Please note that this list is updated on a rolling basis as new information becomes available for FDA to review.

Manufactured in China:

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Respirator Model(s)</th>
<th>Country of Manufacture</th>
</tr>
</thead>
<tbody>
<tr>
<td>3M</td>
<td>8011, 8021, 9501, 9205 - 9502v, 9205v - 9207v, 9310v, 9322, 9322+ - 9322v - 9322v, 9541v, 9542, 9542v, 9515v, 9512v, 9510v, 9502v, 9512v, 9510v, 9502v, 9512v</td>
<td>China</td>
</tr>
<tr>
<td>ACDI/TAIING</td>
<td>N95</td>
<td>China</td>
</tr>
<tr>
<td>AMBIENT SAFETY CO.</td>
<td>N95</td>
<td>China</td>
</tr>
<tr>
<td>B&amp;D PRECISION MANUFACTURING CO. LTD</td>
<td>N95</td>
<td>China</td>
</tr>
<tr>
<td>Changzhou Technology Co.</td>
<td>N95</td>
<td>China</td>
</tr>
<tr>
<td>Dongguan Huan Industrial Co., LTD</td>
<td>N95</td>
<td>China</td>
</tr>
<tr>
<td>HAPAN KONG CHEN Daily Necessities Co., Ltd.</td>
<td>N95</td>
<td>China</td>
</tr>
</tbody>
</table>

For more information, visit [https://www.fda.gov/media/136663/download](https://www.fda.gov/media/136663/download).
KN95 Protective Mask – Certification (Item 2-3)
SureShield is a highly protective, form fitting mask designed to provide peace-of-mind for your employees. Our mask is designed for comfort yet offers a high-level of filter efficiency.

Companies such as McDonalds, United Microelectronics Corp., and TSMC Semiconductor use SureShield to ensure their employees and customers are safe.

SureShield offers a high-level of personal protection
- Three layers of SMMS elastic non-woven fabrics
- Proven Particle Filter Efficiency (PFE) of >99% (Japan Kaken Lab Test Report)
- Proven Bacterial Filter Efficiency (BFE) of >95% (US Nelson Lab Test Report)

**Comparison chart**

<table>
<thead>
<tr>
<th>Mask</th>
<th>BFE</th>
<th>PFE</th>
</tr>
</thead>
<tbody>
<tr>
<td>N95</td>
<td>&gt;95%</td>
<td>&gt;95%</td>
</tr>
<tr>
<td>SureShield</td>
<td>&gt;95%</td>
<td>&gt;99%</td>
</tr>
</tbody>
</table>
Authorization – N95 Equivalent General Protection Mask (Item 2-4)

For face masks, EUA do not need to be submitted. Manufacturers of face masks that are used as described in the lettered issued by the FDA on April 24, 2020 and meet the requirements as outlined in said letter (i.e., are within this section (the Scope of Authorization, Section II)) do not need to take any action, other than complying with the Conditions of Authorization (Section IV) to be authorized under this EUA. FDA’s posting and public announcement of this EUA serves as face mask manufacturers’ notification of authorization. Please see link below for full details of authorization of face masks by the U.S. Food & Drug Administration (FDA).

https://www.fda.gov/media/137121/download
Gowns & Suits

All Information is of May 28, 2020
<table>
<thead>
<tr>
<th>ORDER #’S</th>
<th>PRODUCT TYPE</th>
<th>CERTIFICATION /AUTHORIZATION</th>
<th>TEST/APPLIED STANDARD</th>
<th>MANUFACTURER</th>
<th>UNIT PRICE FOB (USD)</th>
<th>PACKING</th>
</tr>
</thead>
<tbody>
<tr>
<td>3-1</td>
<td>Medical gown &gt;40g/cm² Non-sterilized</td>
<td>NMPA CE FDA</td>
<td>GB19082-2009 CE Class I EU 2017/745 FDA Code: OEA AMII level I</td>
<td>China Mainland</td>
<td>$13.90</td>
<td>40 suits per carton Carton Size: 58cm<em>40cm</em>26cm</td>
</tr>
<tr>
<td>3-2</td>
<td>Medical gown 45g/cm² Sterilized with epoxy ethane</td>
<td>NMPA CE FDA</td>
<td>EN ISO 13485:2016 FDA Code: OEA AATCC42-2013 AATCC127-2013 AMII level III</td>
<td>China mainland</td>
<td>$15.05</td>
<td>40 suits per carton Carton Size: 50cm<em>40cm</em>45cm</td>
</tr>
<tr>
<td>3-3</td>
<td>Protective suit 45g/cm² Non- sterilized</td>
<td>CE FDA</td>
<td>CE Class III GB 1840:2010 ISO 17050-1 FDA class I FDA code: OEA</td>
<td>Taiwan</td>
<td>$22.50</td>
<td>50 suits per carton Carton Size: 58cm<em>37cm</em>45cm</td>
</tr>
<tr>
<td>3-4</td>
<td>Protective suit 65g/cm² Irradiation sterilized</td>
<td>NMPA CE FDA</td>
<td>EU 2016/425 EN 14126:2003 FDA Code: OEA</td>
<td>China Mainland</td>
<td>$27.10</td>
<td>25 suits per carton Carton Size: 60cm<em>40cm</em>40cm</td>
</tr>
</tbody>
</table>
Medical Gown – Single-use, Non-sterile (Item 3-1)

**Product Name:** Isolation gown

**Type:** Uniform code

**Indications For Use:**
The Isolation gown is intended to be worn by healthcare providers or visitors to isolate themselves from patients. Single-use, Non-sterile.

**The material:** SMS

**Each Box Number:** 40

**Box Size:** 22.83 inch * 15.75 inch * 10.24 inch

**Total Quantity:** 2,000,000

**Daily Output:** 60,000

<table>
<thead>
<tr>
<th>Isolation Gown - US Sizes (inches)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Parts</td>
</tr>
<tr>
<td>----------------</td>
</tr>
<tr>
<td>CF length</td>
</tr>
<tr>
<td>Bust</td>
</tr>
<tr>
<td>Sleeve</td>
</tr>
<tr>
<td>Shoulder width</td>
</tr>
</tbody>
</table>
Authorization - Medical Gown – Single-use, Non-sterile (Item 3-1)

<table>
<thead>
<tr>
<th>Device</th>
<th>Non-Surgical Isolation Gown</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulation Description</td>
<td>Surgical apparel</td>
</tr>
<tr>
<td>Definition</td>
<td>A gown intended to protect healthcare patients and personnel from the transfer of microorganisms, body fluids and particulate material</td>
</tr>
<tr>
<td>Physical State</td>
<td>An isolation gown is made of fabric material, either non-woven or woven</td>
</tr>
<tr>
<td>Technical Method</td>
<td>Serves as a physical barrier to the transfer of microorganisms, body fluids and particulate material. Level of barrier protection is nonspecific</td>
</tr>
<tr>
<td>Target Area</td>
<td>An isolation gown covers the torso and clothing and poses a physical barrier to the transfer of microorganisms, body fluids and particulate material</td>
</tr>
<tr>
<td>Regulation Medical Specialty</td>
<td>General &amp; Plastic Surgery</td>
</tr>
<tr>
<td>Review Panel</td>
<td>General Hospital</td>
</tr>
<tr>
<td>Product Code</td>
<td>OEA</td>
</tr>
<tr>
<td>Premarket Review</td>
<td>Gastrointestinal, Obstetric, General Hospital and Urology Devices (OHT3)</td>
</tr>
<tr>
<td>Submission Type</td>
<td>510K Exempt</td>
</tr>
<tr>
<td>Regulation Number</td>
<td>873-0080</td>
</tr>
<tr>
<td>Device Class</td>
<td>1</td>
</tr>
<tr>
<td>Total Product Life Cycle (TPLC)</td>
<td>TPLC Product Code Report</td>
</tr>
<tr>
<td>GMP Exempt?</td>
<td>No</td>
</tr>
<tr>
<td>Summary Malfunction</td>
<td>Eligible</td>
</tr>
</tbody>
</table>

Note: FDA has exempted almost all class I devices (with the exception of reserved devices) from the premarket notification requirement, including those devices that were exempted by final regulation published in the Federal Register on December 7, 1994, and January 16, 1996. It is important to confirm the exempt status and any limitations that apply with 21 CFR Parts 882-892. Limitations of device exemptions are covered under 21 CFR 890, where XXX refers to Parts 892-899.

If a manufacturer's device falls into a generic category of exempted class I devices as defined in 21 CFR Parts 882-892, a premarket notification application and FDA clearance is not required before marketing the device in the U.S. However, these manufacturers are required to register their establishment. Please see the Device Registration and Listing website for additional information.

Implanted Device? No
Life-Sustain/Support Device? No
Third Party Review Not Third Party Eligible
Medical Gown – Sterilized (Item 3-2)
Medical Gown – Sterilized (Item 3-2)
Specifications

Description – Disposable Surgical Gown
Protective clothing suitable for operating rooms, medical clinics, hospital wards, inspection rooms, laboratories or CDC sites for isolation of virus damage and for the protection of medical staff from the transfer of bacteria via blood, urine, saline, bodily fluids or chemicals

Features
➢ Single Use
➢ Secure protection (ultrasonic technology)
➢ Anti-fluid, Anti-alcohol, Anti-blood, Anti-static
➢ Durable
➢ Comfortable, Lightweight and Breathable
➢ Tear-resistant
➢ Flame retardant

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Size</th>
<th>Case Size</th>
<th>Qty per Case</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standard Surgical Gown</td>
<td>S</td>
<td>50x40x45cm</td>
<td>40</td>
</tr>
<tr>
<td>Standard Surgical Gown</td>
<td>M</td>
<td>50x40x45cm</td>
<td>40</td>
</tr>
<tr>
<td>Standard Surgical Gown</td>
<td>L</td>
<td>50x40x45cm</td>
<td>40</td>
</tr>
<tr>
<td>Standard Surgical Gown</td>
<td>XL</td>
<td>50x40x45cm</td>
<td>40</td>
</tr>
<tr>
<td>Standard Surgical Gown</td>
<td>2XL</td>
<td>50x40x45cm</td>
<td>40</td>
</tr>
<tr>
<td>Standard Surgical Gown</td>
<td>3XL</td>
<td>50x40x45cm</td>
<td>40</td>
</tr>
</tbody>
</table>
Authorization – Medical Gown – Sterilized (Item 3-2)
Protective Suit – Non-sterile (Item 3-3)

Feature
- Soft, breathable and comfortable
- Disposable & Convenient

Design
- Sewn seams
- Smooth zipper with zipper flap
- Comes with Hood
- Elastic bands on hood, sleeve openings, and leg openings
- Color: White

Application
- Exposure level as defined by CE approval Type 5B and Type 6B
- Maintenance applications
- Clean room applications

Storage
- Store it in places where is away from moisture and heat

Disposal
- Eco-friendly, can be discarded without causing

Limitation of Use
- This coverall does not offer protection against solvents and mineral acids
- Do not get close to flame or heat. Material melts at about 90°C.

Protective Coverall

<table>
<thead>
<tr>
<th>Size (cm)</th>
<th>Body Height</th>
<th>Body Width</th>
<th>Sleeve Length</th>
</tr>
</thead>
<tbody>
<tr>
<td>F</td>
<td>175 ~ 185</td>
<td>62±1</td>
<td>60±1</td>
</tr>
</tbody>
</table>
Authorization – Protective Suit – Non-sterile (Item 3-3)

Protective Suit – Irradiation Sterilized (Item 3-4)

Designed for medical staff - protection from viruses or bodily fluids from patients; only used for observation areas, not for isolation areas nor ICU, etc. where stringent controls on micro-life & electrostatic disinfecting is in place.

<table>
<thead>
<tr>
<th>Height (cm)</th>
<th>Chest (cm)</th>
<th>Sleeve (cm)</th>
<th>Wrist (cm)</th>
<th>Feet (cm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>165</td>
<td>120</td>
<td>84</td>
<td>18</td>
<td>24</td>
</tr>
<tr>
<td>169</td>
<td>125</td>
<td>86</td>
<td>18</td>
<td>24</td>
</tr>
<tr>
<td>173</td>
<td>130</td>
<td>90</td>
<td>18</td>
<td>24</td>
</tr>
<tr>
<td>178</td>
<td>135</td>
<td>93</td>
<td>18</td>
<td>24</td>
</tr>
<tr>
<td>181</td>
<td>140</td>
<td>96</td>
<td>18</td>
<td>24</td>
</tr>
<tr>
<td>188</td>
<td>145</td>
<td>99</td>
<td>18</td>
<td>24</td>
</tr>
</tbody>
</table>
Authorization - Protective Suit – Irradiation Sterilized (Item 3-4)

Gloves

All Information is of May 28, 2020
<table>
<thead>
<tr>
<th>ORDER #’S</th>
<th>PRODUCT TYPE</th>
<th>CERTIFICATION /AUTHORIZATION</th>
<th>TEST/APPLIED STANDARD</th>
<th>MANUFACTURER</th>
<th>UNIT PRICE FOB (USD)</th>
<th>PACKING</th>
</tr>
</thead>
<tbody>
<tr>
<td>4-1</td>
<td>PVC Glove (XS-XXL)</td>
<td>CE 510 (K) ISO 13485:2016</td>
<td>510 (K) No. K091942</td>
<td>China mainland</td>
<td>$0.20</td>
<td>100pcs per box 10boxes per carton Carton Size: 31.5cm<em>25.8cm</em>24.5cm</td>
</tr>
<tr>
<td>4-2</td>
<td>Nitrile Glove (XS-XXL)</td>
<td>CE 510 (K) ISO 13485:2016</td>
<td>510 (K) No. K091942</td>
<td>China mainland</td>
<td>$0.20</td>
<td>100pcs per box 10boxes per carton Carton Size: 31.5cm<em>25.8cm</em>24.5cm</td>
</tr>
<tr>
<td>4-3</td>
<td>Nitrile Glove</td>
<td>FDA</td>
<td>FDA class I</td>
<td>Thailand</td>
<td>$0.15</td>
<td>TBC</td>
</tr>
</tbody>
</table>
PVC Vinyl Gloves – (XS-XXL) and Certification (Item 4-1)

**Description** – Patient Vinyl Examination Gloves, Powder-free, Non-Sterile

A disposable device intended for medical purposes that is worn on the examiner’s hands or fingers to prevent contamination between patient and examiner.
Description – Patient Nitrile Examination Gloves, Powder-free, Non-Sterile, Blue Color

A disposable device intended for medical purposes that is worn on the examiner’s hands or fingers to prevent contamination between patient and examiner.
Nitrile Gloves – (XS-XXL) (Item 4-3)

**Description** – Disposable Nitrile Patient Examination Gloves – Powder-free, Non-latex, Ambidextrous, Protein-free, Textured
Authorization and Certifications – Nitrile Gloves – (XS-XXL) (Item 4-3)
Ventilators

All Information is of May 28, 2020
## PRODUCT / PRICE SUMMARY – VENTILATORS

<table>
<thead>
<tr>
<th>ORDER #’S</th>
<th>PRODUCT TYPE</th>
<th>CERTIFICATION /AUTHORIZATION</th>
<th>TEST/APPLIED STANDARD</th>
<th>MANUFACTURER</th>
<th>UNIT PRICE FOB (USD)</th>
<th>PACKING</th>
</tr>
</thead>
<tbody>
<tr>
<td>5-1</td>
<td>BMC Y-30T non-invasive</td>
<td>NMPA CE FDA ISO</td>
<td>93/94/EEC</td>
<td>China mainland</td>
<td>$3,484.97</td>
<td>Ventilator (rough weight): 2.5kg 29cm<em>18cm</em>13.4cm</td>
</tr>
<tr>
<td>5-2</td>
<td>BMC GB-B30VT Non-invasive</td>
<td>NMPA CE FDA ISO</td>
<td>93/94/EEC</td>
<td>China mainland</td>
<td>$4,455.39</td>
<td>Ventilator (rough weight): 3.5kg 35cm<em>28cm</em>17cm</td>
</tr>
</tbody>
</table>
BMC Y-30T Non-invasive Ventilator (Item 5-1)

Y-30T
(Target Tidal Volume Function)

Non-invasive ventilator Y-30T is Bi-level PAP (Bi-level Positive Airway Pressure) device intended to provide non-invasive ventilation for patients with Respiratory Insufficiency. It is intended for adult patients by prescription in the home or hospital/institutional environment. With its Target Tidal Volume function and other excellent comfort features and effective performance, it offers each patient personalized ventilation support.
BMC Y-30T Non-invasive Ventilator (Item 5-1)

**Specifications**

**General Info**
- Dimensions: 170 mm × 180 mm × 118 mm
- 290 mm × 180 mm × 134 mm (with the humidifier)
- Weight: 1.5 kg
- 2.5 kg (with the humidifier)

**Water capacity:** 350 mL at recommended water level

**Ramp**
- The ramp time ranges from 0 to 60 minutes

**Humidifier**
- Humidifier Settings: off, 1 to 5 (95°F to 167°F / 35°C to 75°C)
- Humidifier Output: No less than 10 mg H2O/L SpO2
- Range: 0 to 100%

**Pulse Rate**
- Range: 40 to 240

**BPM Sound**

**Pressure Level**
- <30 dB, when the device is working at the pressure of 10 hPa

**Storage**
- SD card can record patient data and fault information

**AC Power Consumption**
- 100 - 240 VAC, 50/60 Hz, Max 2 A

**Key Parameters**
- Target Vt: On/Off
- 150~1500 mL
- Reslex: Patient, Off, 1~3
- Sens.: 1~8
- E Sens.: 1~8
- Res Rate: 3~40
- BPM Ti: 0.3~3.0s
- Rise Time: 1~4

BMC Medical Co., Ltd.
Room 110, Tower A Fengyu Building, No.115 Fucheng Road, Haidian, 100036 Beijing, PEOPLE'S REPUBLIC OF CHINA
Tel: +86-22-8293 9881 / Fax: +86-22-8293 9881 ext. 810
en.bmc-medical.com
To Manufacturers and Other Stakeholders:

This Emergency Use Authorization (EUA) is being issued in response to concerns relating to insufficient supply and accessibility of FDA-cleared ventilators for use in inpatient settings to treat patients during the Coronavirus Disease 2019 (COVID-19) pandemic.

On February 4, 2020, pursuant to section 564(a)(1)(C) of the Federal Food, Drug, and Cosmetic Act (the Act), the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has the potential to affect national security or the health and security of United States citizens living abroad, and that presents the virus that causes COVID-19. Pursuant to section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared, on March 24, 2020, that circumstances exist justifying the authorization of emergency use of medical devices, including ventilatory products, used as medical devices, during the COVID-19 pandemic, subject to the terms of any authorizations issued under that section.

Having concluded that the criteria for issuance of this authorization under section 564(a) of the Act are met, I am authorizing the emergency use of ventilators, noninvasive positive pressure ventilation systems modified for use as ventilators (collectively referred to as "ventilators"), ventilator tubing connectors, and ventilator accessories that FDA determines meet the criteria for safety, performance, and labeling set forth in Sections II and Appendix A for the emergency use in inpatient settings to treat patients during the COVID-19 pandemic, in accordance with the terms of an application from the sponsor of a ventilator, ventilator tubing connector, or ventilator accessory as described in Section II and pursuant to the Conditions of Authorization in Section IV of this letter. Ventilators, ventilator tubing connectors, and ventilator accessories must be used as ventilators, and I intend that the ventilators, ventilator tubing connectors, and ventilator accessories that have been authorized for use in accordance with this EUA be marked with the words "Authorized for Emergency Use" and "Emergency Use Only." The conditions of authorization are designed to meet the requirements of section 564(d)(2) of the Act, as amended by the Biologics Price Competition and Innovation Act of 2003 (BPCIA) (Pub. L. 108-77, Div. E, Title X, section 1001, April 22, 2003) (the BPCIA).

Download the full document here: https://www.fda.gov/media/136528/download
G3 B30VT

G3 B30VT is a bi-level device with S/T mode and target tidal volume feature for patients with respiratory insufficiency.
All new humidifier design keeps the G3 B30VT compact and attractive.

Innovative PUSH water chamber is simple to use.

### Humanized UI Design

<table>
<thead>
<tr>
<th>S/T</th>
<th>Mode</th>
<th>EPAP</th>
<th>IPAP</th>
<th>Res Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.0cmH2O</td>
<td>23.5 L/min</td>
<td>516 mL Vt</td>
<td></td>
<td></td>
</tr>
<tr>
<td>16 bpm</td>
<td>8.4 L/min</td>
<td>1.1 s Ti</td>
<td></td>
<td></td>
</tr>
<tr>
<td>11.8 L/min Leak</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

![Ventilator Image](image_url)
BMC GB-B30VT Non-invasive Ventilator (Item 5-2)

Accessories replacement reminder
Accessories replacement reminder and reminder cycle can be set for mask, air tubing and air filter, so that the consumables can be replaced regularly in time to ensure a better therapy effect.

<table>
<thead>
<tr>
<th>Therapy</th>
<th>Comfort</th>
<th>Alarm</th>
<th>Maintenance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alert Log</td>
<td>&gt;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low Pressure</td>
<td>4.0 cmH₂O</td>
<td></td>
<td></td>
</tr>
<tr>
<td>High Pressure</td>
<td>30.0 cmH₂O</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low RR</td>
<td>6 bpm</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Alarms to make therapy reliable
Various visual and auditory alarming - Leak, High/Low RR, High/Low Pressure, Low Minute Ventilation, Power Failure, etc.
BMC GB-B30VT Non-invasive Ventilator (Item 5-2)

**Specifications**

**Device Size**
- Dimensions (L x W x H): 265 mm × 145 mm × 114 mm
- Weight: 1.7 kg
- Water capacity: To maximum fill line 360 mL

**Heated Humidifier**
- Settings: Off, 1 to 5, Auto (95°F to 154.4°F / 35°C to 68°C)
- Humidifier Output: No less than 15 mg H2O/L

**Sound Pressure Level**
- <26 dB, when the device is working at the pressure of 10 hPa

**Data Storage**
- On board: Summary data, all the time; Detailed airflow data, 1 day.
- SD card: Summary data, all the time; Detailed airflow data, 546 hours.

**Key Parameters**
- Target Vt:
  - On / Off 150~150 0 mL
- I Sens.:
  - 1~8 E
- Sens.:
  - 1~8
- Rise Time:
  - 1~4 Res
- Rate:
  - 3~40 BPM
- Ti: 0.3-3.0s
Authorization and Certification – BMC GB-B30VT Non-invasive Ventilator (Item 5-2)

March 24, 2020

To Manufacturers and Other Stakeholders:

This Emergency Use Authorization (EUA) is being issued in response to concerns relating to serious risk and ineluctable risks to public health and safety of COVID-19 (coronavirus disease 2019) in the United States.

On February 4, 2020, pursuant to Section 564(f)(3) of the Federal Food, Drug, and Cosmetic Act (the Act), the Commissioner of the Food and Drug Administration (CDCA) determined that there is a reasonable assurance of safety and effectiveness of the device and that its use in the emergency use of respiratory support devices may be critical to the public health in response to COVID-19. Pursuant to Section 564 of the Act, on the basis of such determination, the Commissioner of the CDCA on March 24, 2020, determined and established the conditions for the emergency use of the device, including alternative products used as medical devices, during the COVID-19 pandemic, subject to the terms of any authorization issued under this section.

Having consulted the criteria for issuance of the authorization under section 564(e) of the Act as are set forth in the act and in the act, the Commissioner determined that the conditions for the emergency use of the device are met.

The conditions for the emergency use of the device are set forth in Section II of this letter. The conditions for the emergency use of the device are as follows:

1. The conditions for the emergency use of the device are set forth in Section II of this letter.
2. The conditions for the emergency use of the device are set forth in Section II of this letter.
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9. The conditions for the emergency use of the device are set forth in Section II of this letter.
10. The conditions for the emergency use of the device are set forth in Section II of this letter.

https://www.fda.gov/media/136528/download
Company Profile

- Founded in 2001
- The leader in the development of home respiratory care devices and services in China
- Keenly seeking to Become the first choice in respiratory care
- Global Rank: TOP 5
- Annual capacity: 400,000 units
- 350 employees, around 100 R&D team under leadership from Tsinghua University, Chinese Academy of Sciences and Xi’an Jiaotong University
Face Shields

All Information is of May 28, 2020
## PRODUCT / PRICE SUMMARY – FACE SHIELDS

<table>
<thead>
<tr>
<th>ORDER #’S</th>
<th>PRODUCT TYPE</th>
<th>CERTIFICATION /AUTHORIZATION</th>
<th>TEST/APPLIED STANDARD</th>
<th>MANUFACTURER</th>
<th>UNIT PRICE FOB (USD)</th>
<th>PACKING</th>
</tr>
</thead>
</table>
| 6-1       | Face Shield FS-XHY01 FS-XHY02 | NMPA ISO FDA CE | FDA class I FDA code: KPY | China mainland | $1.00 | INDIVIDUAL POLYBAGS  
100pcs per carton  
Carton Size: 400*340*350mm  
Net weight: 4.2kg; Gross weight: 5.2kg  
200pcs per carton  
Carton Size: 400*690*350mm  
Net weight: 8.0kg; Gross weight: 9.0kg |

- **FOB (USD):** Prices are in USD.
- **Packaging:**
  - Individual polybags: 100 pcs per carton, size 400*340*350 mm, net weight 4.2 kg, gross weight 5.2 kg.
  - 200 pcs per carton, size 400*690*350 mm, net weight 8.0 kg, gross weight 9.0 kg.
# Face Shields - Specifications (Item 6-1)

<table>
<thead>
<tr>
<th>DESC</th>
<th>SIZE</th>
<th>MATERIAL</th>
<th>SPECIFICATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>FACE</td>
<td>330*220MM</td>
<td>NEW PET</td>
<td>PET double sided anti-fog</td>
</tr>
<tr>
<td>SPONGE</td>
<td>250<em>38</em>30mm</td>
<td>POLYURETHANE</td>
<td>Environment friendly sponge</td>
</tr>
<tr>
<td>ELASTIC BAND</td>
<td>310*20mm</td>
<td>POLYESTER FIBER</td>
<td>Enough elastic</td>
</tr>
<tr>
<td>POLY BAG</td>
<td>406*272mm</td>
<td>CPP</td>
<td>Transparent bag</td>
</tr>
<tr>
<td>PACKING INFORMATION</td>
<td>400<em>340</em>350mm</td>
<td>K=K</td>
<td>INDIVIDUAL POLYBAG, 100pcs/carton N.W.:4.2kg, G.W.:5.2kg</td>
</tr>
<tr>
<td></td>
<td>400<em>690</em>350mm</td>
<td>K=K</td>
<td>INDIVIDUAL POLYBAG, 200pcs/carton N.W.:8.0kg, G.W.:9.0kg</td>
</tr>
</tbody>
</table>
Face Shields – Manufacturing and Warehouse (Item 6-1)
The above certificates are to prove that we are a professional manufacturer with guaranteed quality. GSV factory inspection certificate can prove that our production environment and process are world-class.
This certificate proves that we have the right to export the face shields, which is one of the documents to be examined by the Chinese customs.
Face Shields - Certifications (Item 6-1)

https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-useauthorizations#covid19ppe
Most devices require a 510(k) submission to the Center for Devices and Radiological Health (CDRH) within the FDA. The group within the CDRH consists of a panel of scientific experts that review 510(k) submissions.

Medical Device Classification

- Is the product a medical device?
- How do we determine which classification the device falls under?
- What are the specific regulations for this class of device?

These are just a few of the questions a company needs to address when applying for product approval in various markets.

We can help your company confidently define the classification of your product. Also, because of our experience with devices from all class types, we can develop the most efficient regulatory approval process for your company to follow.

510k Imports will carefully review the intended use of the device, indications for use, possible exemptions for your device, the risk level of the device, and other factors before determining the specific classification.

FDA 510(k) submissions

- Indications for Use
- 510k Device Description
- Performance Compliance 21 CFR 807.87 D
- Class III Certification and Summary (for Class III only)
- Final Certification and Disclosure Statement for 510k notifications with Clinical Studies
- 510k Kit Certification
- Sterilization Methods
- Software Documentation
Ongoing Post-market Surveillance and MDR

• We can assist companies if any problems arise after your medical device has entered the market. We will take effective measures to re-establish compliance as quickly as possible.

• 510k imports will provide surveillance services including, vigilance reporting, responses to FDA 483s and warning letters, development of product recall strategies, complaint handling, failure investigation, problem reporting, device tracking, and any other necessary measures to assure compliance in the U.S. or international markets.

Premarket Approval Application

• The FDA Premarket Approval Process is required to ensure the safety and effectiveness of Class III medical devices. Class III devices are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury.

• Due to the invasive nature of Class III products, the Premarket Approval Process is meticulously executed by a scientific review board. Prior to marketing a device, an applicant must receive Premarket Approval from the FDA. FDA regulations provide 180 days to review the PMA and make a determination. However, in reality the review time is normally longer. Before approving or denying a PMA, the appropriate FDA advisory committee may review the PMA at a public meeting and provide FDA with the committee’s recommendation on whether FDA should approve the submission.

• Methodize can help you throughout the process of Applying for Premarket Approval. Our services include Pre-Investigational Device Exemption, Investigational Device Exemption, Premarket Approval, Quality System Inspection, and final FDA registration of the device.
Please contact us with any questions

Contact: LaTatia Colbert-Reed
Phone: 203-285-6512
Email: latatia@biophective.com or latatia@510kimports.com

510k imports, llc  510kimports.com
Venture Partners

Tony Chu
With over 20 years of cross-border transaction experience in US/EU and Chinese chemical and pharmaceutical industries
- Venture Partner 510K Imports
- Co-Founder and Managing Partner of TPP Healthcare
- Founder of Zhejiang Phoenix Valley Co Ltd
- Co-Founder and board member of TPP Technopark
Current Board Member for
- Eastar Chemical Corp
- Hestia (Wuxi)
- PT Inodia (Indonesia);
And advises numerous publicly listed Chinese pharmaceutical companies and Investment funds

Xielong Luo
- Venture Partner 510K Imports
- Partner TPP Healthcare;
- Executive Director of BOAO Asia International Health Forum,
- Director of Zhejiang Yangtze Delta Pharmaceutical Research and Development Center,
- Vice Chairman of Chinese Pharmaceutical Enterprises Association
- Vice Chairman of Chinese OTC Association
Previously, worked as
- Chairman of Zhejiang Wansheng and Chinese Medical Research Developing Center
- President of Beijing Renhe
- Hangzhou National Biology Pharmaceutical Investment Corporation and Beijing Medical University Wafang Technology Development Corporation and Shenzhen Yizhou High tech Industry;
- Vice president of HK Yizhou Corporation

Ivan Lo
Venture Partner 510K Imports
Founder of Hestia nutrition
over 22 years of experience in MNCs including Novartis, Pfizer health pharmaceuticals and NUTRICIA medical nutrition;
Experience in
- supply chain, finance, new product management
- computer management, market access, product registration southeast Asia and pediatric sales and marketing;
Set up a series of hospital/retail management systems to achieve rapid sales growth, reaching $100 million; make Caltrate became the world’s flagship product in 2009;
Improved cash flow and profit, enabling NUTRICIA China to deliver outstanding global performance over the past five years, with profit growth of over 50% and the best cash flow management in the world;
Awarded the leading figure of Wuxi high-tech zone in 2018, and won the financial support of the government in R&D;