December 16, 2020

Beijing Biosis Healing Biological Technology Co., Ltd
℅ Diana Hong
General Manager
Mid-Link Consulting Co. Ltd
P.O.Box 120-119
Shanghai, 200120
China

Re: K202029
Trade/Device Name: Medical Surgical Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: July 15, 2020
Received: July 22, 2020

Dear Diana Hong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For CAPT Elizabeth Claverie, M.S.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K202029

Device Name
Medical Surgical Mask

Indications for Use *(Describe)*
The medical surgical mask is intended for single use by operating room personnel and other general healthcare workers to protect both patients and healthcare workers against transfer of microorganisms, blood and body fluids, and particulate materials.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

The assigned 510(k) Number: K202029

1. Sponsor Identification

Beijing Biosis Healing Biological Technology Co., Ltd.
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Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Ying Xu (Alternative Contact Person)

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Email: info@mid-link.net

Date of Preparation: 12/16/2020

2. Identification of Proposed Device

Trade Name: Medical Surgical Mask
Common Name: Surgical Mask
Regulation Name: Surgical Apparel

3. Regulatory Information

Classification: II;
Product Code: FXX;
Regulation Number: 21CFR 878.4040
Review Panel: General Hospital

4. Identification of Predicate Device

Manufacturer: V&Q Manufacturing Corporation
510(k) Number: K173062
Product Name: Non Woven Face Mask (Models: VQN0185W (earloop) and VQN0185B (ties))

5. Indication for use:

The medical surgical mask is intended for single use by operating room personnel and other general healthcare workers to protect both patients and healthcare workers against transfer of microorganisms, blood and body fluids, and particulate materials.

6. Device Description:

The proposed device, Medical Surgical Mask is a three-layer, single-use, flat-pleated mask. The mask body is made of 25g/m^2 PP non-woven cloth. The mask contains tie strings or ear loops to secure the mask over the users' mouth and face and includes a nosepiece to provide a firm fit over the nose. Ear loops are made of Nylon and PU, and tie strings are made of Nylon. The nose clip which is made of Iron strip covered by polypropylene covering. The device is provided in sterile.

7. Summary of Technological Characteristics

Table 1 Comparison of Medical Surgical Mask

ITEM	Proposed Device K202029	Predicate Device K173062	Remark
Product Code	FXX	FXX	Same
Regulation No.	21 CFR 878.4040	21 CFR 878.4040	Same
Class	II	II	Same
Indication for Use	The medical surgical mask is intended for single use by operating room personnel and other general healthcare workers to protect both patients and healthcare workers against transfer of microorganisms, blood and body fluids, and particulate materials.	Non Woven Face Mask (Models: VQN0185W (earloop) and VQN0185B (ties)) is intended for single use by operating room personnel and other general healthcare workers to protect both patients and healthcare workers against transfer of microorganisms, blood and body fluids, and particulate materials.	Same
Mask style	Flat pleated	Flat pleated	Same
Mask color	Blue	Blue	Same
Design feature	Earloop or tie-on	Earloop or tie-on	Same
Dimension (mm)	120mm×70mm 145mm×90mm 175mm×95mm	175mm×95mm	Different
ASTM F2100 Level	Level 2	Level 2	Same
Performance			
Fluid resistance	Pass at 120mmHg	Pass at 120mmHg	Same
Particulate efficiency level	Average 98.87%	Average 99.74% at 0.1μm	Similar
Bacterial filtration level	Average 99.46%	Average 99.4%	Similar
Differential pressure	Average 3.72mmH_2O/cm^2	Average 2.7mmH_2O/cm^2	Similar
Flammability	Class 1	Class 1	Same
Label/Labeling	Complied with 21 CFR part 801	Complied with 21 CFR part 801	Same
Patient Contacting Material			
ear strap	Nylon and PU	Urethane elastic fiber or spun-bond polypropylene	Different

nose clip	Iron strip covered by polypropylene covering	White aluminum strip covered by PP covering	Different
mask body	25g/m^2 PP non-woven cloth	Spun-bond polypropylene	Different
Biocompatibility			
Cytotoxicity	No Cytotoxicity	No Cytotoxicity	Same
Sensitization	No Sensitization	No Sensitization	Same
Irritation	No Irritation	No Irritation	Same
Sterility	Sterile	Non-sterile	Different

8. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- ISO 10993-7:2008 Biological Evaluation of Medical Device- Part 7: Ethylene Oxide Sterilization Residuals
- ASTM F88/F88M-15, Standard Test Method For Seal Strength Of Flexible Barrier Materials.(Sterility)
- ASTM F1929-15 Standard Test Method for Detecting Seal Leaks in Porous Medical Package by Dye Penetration
- ISO 10993-5:2009 Biological evaluation of medical device- Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2010 Biological evaluation of medical device- Part 10: Tests for irritaion and skin sensitization
- ASTM F1862/F1862M-17 Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity)
- ASTM F2299/F2299M-03 (2017) Standard Test Method for Determining the Initial Efficiency of Material Used in medical Face Masks to Penetration by Particulates using Latex Spheres
- ASTM F2101-2017 Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus

9. Clinical Test Conclusion

No clinical study is included in this submission.

10. Conclusion

The summary includes the conclusions drawn from the nonclinical and clinical tests (discussed above) that demonstrate that the proposed device is as safe, as effective, and performs as well as or better than the predicate device.