January 6, 2021

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

Re: K202844
Trade/Device Name: Medical Surgical Gowns
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FYA
Dated: December 10, 2020
Received: December 9, 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)*
K202844

Device Name
Medical Surgical Gowns

Indications for Use *(Describe)*
The Medical Surgical Gowns is intended to be worn by operating room personnel during surgical procedure to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material.

Per ANSI/AAMI PB70:2012 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities, the Medical Surgical Gowns met the requirements for Level 3 classification.

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 K202844

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

The assigned 510(k) Number: K202844

1. Date of Preparation: 1/5/2021

2. Sponsor Identification

BEIJING BIOSIS HEALING BIOLOGICAL TECHNOLOGY CO., LTD
No.6 plant west, Valley No.1 Bio-medicine Industry Park, Daxing District, 102600 Beijing, China.

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3. Designated Submission Correspondent

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

4. Mid-Link Consulting Co., Ltd
P.O. Box 120-119, Shanghai, 200120, China

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Fax: 360-925-3199
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5. Identification of Proposed Device

Trade Name: Medical Surgical Gowns
Common Name: Surgical Gown;

Regulatory Information

Classification Name: Surgical Gown;
Classification: II;
Product Code: FYA;
Regulation Number: 21CFR 878.4040
Review Panel: General & Plastic Surgery;

Indication for Use:

The Medical Surgical Gowns is intended to be worn by operating room personnel during surgical procedure to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material.

Per ANSI/AAMI PB70:2012 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities, the Medical Surgical Gowns met the requirements for Level 3 classification.

Device Description:

The proposed device is a poly-reinforced surgical gown, the critical zone is front chest and sleeves. The critical zone is reinforced with PP/PE composite laminated material and the reinforced layer is attached with the gown by ultrasonic welding. The proposed device is available in five different sizes, include S-160, M-165, L-70, XL-175, XXL-180, and XXXL-185. Per ANSI/AAMI PB70:2012 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities, the proposed devices can meet the requirements for Level 3 classification. The proposed devices are disposable medical devices and provided in sterile.

6. Identification of Predicate Device

510(k) Number: K172987
Product Name: Surgical Gown (AG1001, AG2001, AG3001)

7. Technological Characteristic Comparison Tables

Table 1 Technological Characteristic Comparison

ITEM	Proposed Device K202844	Predicate Device K172987	Remark
Product Code	FYA	FYA	Same
Regulation Number	21 CFR 878.4040	21 CFR 878.4040	Same
Class	II	II	Same
Indication for use	The Medical Surgical Gowns is intended to be worn by operating room personnel during surgical procedure to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material. Per ANSI/AAMI PB70:2012 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities, the Medical Surgical Gowns met the requirements for Level 3 classification.	Surgical gown is intended to be worn by operating room personnel during surgical procedure to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material. Per ANSI/AAMI PB70:2012 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities, the AG series surgical gowns met the requirements for Level 3 classification.	Same
Style	Poly-reinforced	Non-reinforced Fabric-reinforced Poly-reinforced	Similar
Durability	Disposable	Disposable	Same
Color	Blue	Blue	Same
Labeling	Conform with 21CFR Part 801	Conform with 21CFR Part 801	Same

Table 2 Technological Characteristic Comparison

ITEM	Proposed Device	Predicate Device	Remark
Size	S, M, L, XL, XXL, XXXL	S, M, L, XL, XXL	Similar
Break strength	>20N	>20N	Same
Tear strength	>20N	>30N	Similar
Air permeability	>15 $cm^3/s/cm^2$ (29 ft3/min/ft2)	>30 ft3/min/ft2	Similar
Lint	Log_{10}＜4	Log_{10}＜4	Same
Flammability	Class I	Class I	Same
Hydrostatic pressure	>50 cm	>50 cm	Same
Water impact	≤1.0 g	≤1.0 g	Same
Material	SMS nonwoven, polyethylene, polyester	SMMMS, polypropylene, polyethylene, polyester	Similar
Level	Level 3 per AAMI PB 70	Level 3 per AAMI PB 70	Same
Biocompatibility			
Cytotoxicity	No Cytotoxicity	No Cytotoxicity	Same
Skin Irritation	No Irritation	No Irritation	Same
Sensitization	No Sensitization	No Sensitization	Same
Sterile	Ethylene Oxide (EO), SAL=10^{-6}	Ethylene Oxide (EO), SAL=10^{-6}	Same

8. Non-Clinical Test Conclusion

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

- 16 CFR Part 1610 Standard for the Flammability of Clothing Textiles;
- AATCC 127: 2017 Water Resistance: Hydrostatic Pressure Test;
- AATCC 42:2017 Water Resistance: Impact Penetration Test;
- ISO 9073-10:2003 Textiles-Test Methods for Nonwovens-Part 10: Lint and Other Particles Generation in the Dry State;
- ASTM D1683/D1683M-17:2017/(R) 2018 Standard Test Method for Failure in Sewn Seams of Woven Fabrics
- ASTM D 5587-15:2015 Standard Test Method for Tearing Strength of Fabrics by Trapezoid Procedure;
- ASTM D 5034-09:2017 Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test);
- ASTM D737-18:2018 Standard Test Method for Air Permeability of Textile Fabrics;
- ASTM F88/F88M-15 Standard Test Method for Seal Strength of Flexible Barrier Materials;

- ASTM F1929-15 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration;
- ISO 10993-7:2008 Biological Evaluation of Medical Devices-Part 7: Ethylene Oxide Sterilization Residuals;
- ISO 10993-5:2009 Biological Evaluation of Medical Devices-Part 5: Tests for in Vitro Cytotoxicity;
- ISO 10993-10:2010 Biological Evaluation of Medical Devices-Part 10: Tests for Irritation and Skin Sensitization;

9. Clinical Test Conclusion

No clinical study is included in this submission.

10. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the device is as safe, as effective, and perform as well as or better than the legally marketed predicate device.