December 31, 2020

B.J.ZH.F.Panther Medical Equipment CO., LTD.
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O. Box. 120-119
Shanghai, 200120
China

Re: K202706
Trade/Device Name: Surgical Gown (Sterile), Surgical Gown (Non-sterile)
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FYA
Dated: November 23, 2020
Received: December 3, 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); 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: Elizabeth F. Claverie-Williams, MS
Acting 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)*
K202706

Device Name
Surgical Gown (Sterile), Surgical Gown (Non-sterile)

Indications for Use *(Describe)*
Surgical gowns are 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 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.

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510(k) Summary K202706

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

The assigned 510(k) Number: K202706

1. Date of Preparation: 12/30/2020

2. Sponsor Identification

B.J.ZH.F.PANTHER MEDICAL EQUIPMENT CO., LTD.

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3. Designated Submission Correspondent

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

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5. Identification of Proposed Device

Trade Name: Surgical Gown (Sterile), Surgical Gown (Non-sterile)
Common Name: Surgical Gown

Regulatory Information

Classification Name: Gown, Surgical
Classification: II;
Product Code: FYA;
Regulation Number: 21 CFR 878.4040
Review Panel: General Hospital;

Indication for use:

Surgical gowns are 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 surgical gowns met the requirements for Level 3 classification.

Device Description:

The proposed devices are intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material. The proposed devices are single use, disposable medical devices and can be provided in sterile and non-sterile two types. Both the sterile and non-sterile surgical gowns are available in six sizes, including S, M, L, XL, XXL and XXXL. For non-sterile surgical gowns, they shall be sterilized by EO prior to use.

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 meet the requirements for Level 3 classification.

6. Identification of Predicate Device

510K Number: K192290
Product Name: 50g SMS Standard Surgical Gown;
45g SMS Surgical Gown with Reinforcement;
68g BVB Surgical Gown;

7. Identification of Reference Device

510(k) Number: K172987
Product Name: Surgical Gown

8. Technological Characteristic Comparison Tables.

Table 1 Technological Characteristic Comparison

Item	Subject Device K202706	Predicate Device K192290	Reference Device K172987	Remark
Product Code	FYA	FYA	FYA	Same
Regulation No.	21CFR 878.4040	21CFR 878.4040	21CFR 878.4040	Same
Class	II	II	II	Same
Indication for Use	Surgical gowns are 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 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, SMS Standard Surgical Gown and SMS Surgical Gown with Reinforcement met the requirements for Level 3 classification; BVB Surgical Gown and BVB Splicing Surgical Gown met the requirements for Level 4 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.	Similar
Style	Non-reinforced	Non-reinforced/Reinforced	Non-reinforced/Reinforced	Similar
Durability	Disposable	Disposable	Disposable	Same

Color	Blue	Blue	Blue	Same
Labeling	Conform with 21CFR Part 801	Conform with 21CFR Part 801	Conform with 21CFR Part 801	Same

Table 2 Technological Characteristic Comparison

Item	Subject Device K202706	Predicate Device K192290	Reference Device K172987	Remark
Weight per square (g)	55g/m^2	50g/m^2, 45g/m^2, 68g/m^2	44g/m^2	Similar
Size	S, M, L, XL, XXL, XXXL	M, L, XL, XXL, XXXL, XXXL-XLONG	XL	Similar
Flammability	Class I	Class I	Class I	Same
Hydrostatic pressure	>50 cm	>50 cm	>50 cm	Same
Water impact	≤1.0 g	≤1.0 g	≤1.0 g	Same
Breaking strength	>20N	>20N	>20N	Same
Tearing strength	>20N	>20N	>30N	Similar
Linting	Log_{10}<4	Log_{10}<4	Log_{10}<4	Same
Air permeability	>30 ft^3/min/ft^2	>15cm^3/s/cm^2 (29 ft^3/min/ft^2)	>30 ft^3/min/ft^2	Similar
Material	SMS polypropylene nonwoven + Polyester	SMS nonwoven, Laminated material, white knitted cuff, white spun-bond, and BVB	SMS polypropylene nonwoven	Similar
Level	Level 3 per AAMI PB 70	Level 3, Level 4 per AAMI PB 70	Level 3 per AAMI PB 70	Similar
Biocompatibility				
Cytotoxicity	No Cytotoxicity	No Cytotoxicity	No Cytotoxicity	Same
Irritation	No Irritation	No Irritation	No Irritation	
Sensitization	No Sensitization	No Sensitization	No Sensitization	
Sterile	Sterile/Non-sterile	Sterile	Non-sterile	Similar

9. 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 subject 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:2017/(R)2018 Standard Test Method for Failure in Sewn Seams of Woven Fabrics;
- ASTM D5587:2019 Standard Test Method for Tearing Strength of Fabrics by Trapezoid Procedure;
- ASTM D5034:2017 Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test);
- ASTM D737:2018 Standard Test Method for Air Permeability of Textile Fabrics;
- ASTM F88/F88M:2015 Standard Test Method for Seal Strength of Flexible Barrier Materials;
- ASTM F1929:2015 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;

10. Clinical Test Conclusion

No clinical study is included in this submission.

11. Conclusion

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