December 16, 2021

Weihai Dishang Medical Technology Co., Ltd
Ricky Xia
Manager
Room 406-409, Block C, No.213 Torch Road,
Torch High-tech Industrial Development Zone
Weihai, Shandong 264209
China

Re: K210355
Trade/Device Name: Surgical Gown, Model: surgical gown-hp-3
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FYA
Dated: December 10, 2021
Received: December 15, 2021

Dear Ricky Xia:

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 Clarence W. Murray, III, PhD
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)*
K210355

Device Name
Surgical Gown, Model: surgical gown-hp-3

Indications for Use *(Describe)*
The 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 Surgical Gown meets the requirements for Level 3 classification.

The Surgical Gown is single use, disposable medical device provided non-sterile. The Surgical Gowns is to be sold to re-packager/re-labeler establishments for ethylene oxide (EtO) sterilization according to ISO 11135 prior to marketing to the end user.

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.

K210355

510(K) Summary

Prepared in accordance with the requirements of 21 CFR Part 807.92

Prepared Date: December 10, 2021

1. Submitter's Information

The submitter of this pre-market notification is:

Name:	Weihai Dishang Medical Technology Co.,Ltd
Address:	Room 406-409,Block C,No.213 Torch Road,Torch High-tech Industrial Development Zone,Weihai,Shandong China
Contact person:	Ricky.xia
Title:	Manager
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Tel:	+86- 18663126766

2. Device Identification

510(K) number:	K210355
Trade/Device Name:	Surgical Gown, Model: surgical gown-hp-3
Common name:	Gown, Surgical
Regulation Number:	878.4040
Regulation Name:	Surgical apparel
Regulation Class:	Class II
Panel:	General Hospital
Product Code:	FYA

3. Predicate Device

510(K) number:	K202706
Device Name:	Surgical Gown
Manufacturer:	B.J.ZH.F.Panther Medical Equipment CO., LTD.
Common name	Gown, Surgical
Regulation Number:	878.4040
Regulation Name:	Surgical apparel
Regulation Class:	Class II
Panel:	General Hospital
Product Code:	FYA

4. Device Description

The proposed devices have a SMS design that provides a PB70:2012 level 3 Liquid Barrier Performance Barrier.

The proposed devices are single use, disposable medical devices and can be provided in non-sterile. These surgical gowns are available in six sizes, including S, M, L, XL, XXL and XXXL.

5. Indication for use

The 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 Surgical Gown meets the requirements for Level 3 classification.

The Surgical Gown is single use, disposable medical device provided non-sterile. The Surgical Gown is to be sold to re-packager/re-labeler establishments for ethylene oxide (EtO) sterilization according to ISO 11135 prior to marketing to the end user.

6. Compared to Predicate Device

Compared to the predicate device, the subject device has the same intended use, similar product design, same performance effectiveness, performance safety as the predicate device, the comparison is listed in below table:

Comparisons	Proposed Device surgical gown-hp-3 K210355	Predicate Device K202706	remark
Name	Surgical Gown	Surgical Gown (Non-sterile)	/
Model	surgical gown-hp-3	/	/
Product code	FYA	FYA	Same
Regulation No.	21 CFR 878.4040	21 CFR 878.4040	Same
Class	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. The Surgical Gown is single use, disposable medical device provided non-sterile. The Surgical Gown is to be sold to re-packager/re-labeler establishments for ethylene oxide (EtO) sterilization according to ISO 11135 prior to marketing to the end user.	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.	Same
Level	3	3	Same
Style	Non-reinforced	Non-reinforced	Same
Use	Disposable	Disposable	Same
Color	Blue	Blue	Same
Weight per square(g)	45 g/m^2	55 g/m^2	Similar, see note 1
Size	S, M, L, XL, XXL, XXXL	S, M, L, XL, XXL, XXXL	Same
Material	SMS polypropylene nonwoven	SMS polypropylene nonwoven + Polyester	Similar, see note 1

Performance					
Test item		Test standard	**surgical gown-hp-3**	**Predicate Device K202706**	Remark
Water Resistance	Impact penetration	AATCC TM42-2017e	⩽1.0g	⩽1.0g	Same Meet standard requirement
	Hydrostatic resistance	AATCC 127 - 2017 (2018)	⩾50cm	⩾50cm	Same Meet standard requirement
Tensile Strength		ASTM D5034-09(2017),	≥30N(7 lbf)	＞20N	Meet standard requirement See note 2
Tearing Strength		ASTM D5733-1999	≥10N(2.3 lbf)	＞20N	Meet standard requirement See note 2
Seam Strength		ASTM D1683/D1683M-2011	≥30N(7 lbf)	/	Meet standard requirement See note 2
Flammability		16 CFR Part 1610	Class 1	Class 1	Same

Biocompatibility				
Test item	Test standard	**surgical gown-hp-3**	**Predicate Device K202706**	Remark
Cytotoxicity	ISO 10993-5:2009	No Cytotoxicity	No Cytotoxicity	Same
Skin sensitization	ISO 10993-10:2010	No Irritation	No Irritation	Same
Skin irritation		No Sensitization	No Sensitization	Same
Sterile	/	non-sterile	Sterile/non-sterile	See Note 3

Note 1: There is a little difference in material. We had evaluated performance and biocompatibility in according to ANSI AAMI PB70:2012, ASTM F2407-20, ISO 10993-5 and ISO 10993-10, and the result shows no new risk arise.

Note 2：Because of the update of version of ASTM F2407, in new version of the standard, the test items, tensile strength, tearing strength and seam strength are changed from optional to mandatory, and specify requirement of each test item. The subject devices meet the requirement of new version standard.

Note 3: The subject device is non-sterile surgical gown that are required processing during their use-life.

7. Performance Data

Clinical test:

Clinical testing is not required.

Non-clinical data

Performance:

1. ANSI AAMI PB70:2012 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities

2. ASTM F2407-20 Standard Specification for Surgical Gowns Intended for Use in Healthcare Facilities

Test item		Test standard	Criteria	surgical gown-hp-3
Water Resistance	Impact penetration	AATCC TM42-2017e	⩽1.0g	Pass
	Hydrostatic resistance	AATCC 127 -2017 (2018)	⩾50m	Pass,Meet level 3 requirment
Tensile Strength		ASTM D5034-09(2017),	≥30N(7 lbf)	Pass
Tearing Strength		ASTM D5733-1999	≥10N(2.3 lbf)	Pass
Seam Strength		ASTM D1683/ D1683M-2011	≥30N(7 lbf)	Pass
Flammability		16 CFR Part 1610	Class1	Pass

Biocompatibility:

1. ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro
2. ISO 10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.

Test item	Test Standard	Criteria	Results
In Vitro Cytotoxicity	ISO 10993-5: 2009	Under conditions of the study, the test article must not show potential toxicity.	Pass – Under the condition of the test, the test article was found to be non-toxic
Skin Sensitization	ISO 10993 -10: 2010	Under the conditions of the study, the test article must be found to be non-sensitizing.	Pass - Under the condition of the test, the test article was found to be non-sensitizing
Skin Irritation test	ISO 10993 -10: 2010	Under the conditions of the test, the test article must be found to be non- irritating	Pass - Under the conditions of the test, the test article was found to be non- irritating

9. Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(K) submission K210355, the Surgical Gown, model: surgical gown-hp-3, is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K202706.