September 29, 2022

Allmed Medical (Hubei) Protective Products Co., Ltd
℅ Ivy Wang
Technical Manager
Shanghai SUNGO Management Consulting Company Limited.
14th Floor, 1500# Central Avenue
Shanghai, Shanghai 200122
China

Re: K221637
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: September 2, 2022
Received: September 2, 2022

Dear Ivy Wang:

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,

Bifeng Qian, M.D., Ph.D.
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
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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)*
K221637

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

Indications for Use *(Describe)*
The proposed 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.

Non-sterile gowns are to be sold to re-packager/re-labeler establishments for ethylene oxide (EtO) sterilization according to ISO 11135-1 prior to marketing to the end users and sterile surgical gowns are to be sold directly to the end users after EtO sterilization validation to ISO 11135-1.

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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Allmed Medical (Hubei) Protective Products Co., Ltd
No.29 Dong Hu Road, Majiadian Town, Zhijiang City, Hubei, China

510(K) Summary

K221637

(As requirement by 21 CFR 807.92)

Date prepared: 29th, September, 2022

A. Applicant:

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B. Device:

Trade Name: Surgical Gown (Sterile); Surgical Gown (Non-sterile)
Common Name: Surgical Gown
Model: S, M, L, XL, XXL and XXXL

Regulatory Information
Classification Name: Gown, Surgical
Classification: Class II
Product code: FYA
Regulation Number: 21 CFR 878.4040
Review Panel: General Hospital

C. Predicate device:

K202706
B.J.ZH.F.PANTHER MEDICAL EQUIPMENT CO., LTD.
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

D. Indications for use of the device:

The 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.

Non-sterile gowns are to be sold to re-packager/re-labeler establishments for ethylene oxide (EtO) sterilization according to ISO 11135-1 prior to marketing to the end users and sterile surgical gowns are to be sold directly to the end users after EtO sterilization validation to ISO 11135-1.

E. Device Description:

The proposed surgical gowns 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 blue colored and 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.

The proposed surgical gowns are constructed of a SMS nonwoven material (spunbond +meltblown + spunbond nonwovens) and has been tested according to ANSI/AAMI PB70:2012 Liquid Barrier Performance and Classification of Protective Apparel and Drapes Intended for Use in Health Care Facilities and meets AAMI Level 3. It is a kind of non-reinforced surgical gown.

F. Comparison Tables of Proposed and Predicate Devices

Table 1 General Comparison of Proposed and Predicate Devices

Item	Proposed Device	Predicate Device	Result
510K #	K221637	K202706	-
Manufacturer	Allmed Medical (Hubei) Protective Products Co., Ltd	B.J.ZH.F.PANTHER MEDICAL EQUIPMENT CO., LTD.	-
Product Name	Surgical Gown (Sterile); Surgical Gown (Non-sterile)	Surgical Gown (Sterile); Surgical Gown (Non-sterile)	Same
Level	Level 3	Level 3	Same

Product Code	FYA	FYA	Same
Regulation Number	21 CFR 878.4040	21 CFR 878.4040	Same
Indications for use	The 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. Non-sterile gowns are to be sold to re-packager/re-labeler establishments for ethylene oxide (EtO) sterilization according to ISO 11135-1 prior to marketing to the end users and sterile surgical gowns are to be sold directly to the end users after EtO sterilization validation to ISO 11135-1.	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
Style	Non-reinforced	Non-reinforced	Same
Durability	Disposable	Disposable	Same
Color	Blue	Blue	Same
Labeling	Conform with 21 CFR Part 801	Conform with 21 CFR Part 801	Same

Table 2 Performance Comparison of Proposed and Predicate Devices

Item	**Proposed Device**	**Predicate Device K202706**	**Result**
Weight per square (g)	41±3g/m^2	55g/m^2	Similar
Size	S, M, L, XL, XXL, XXXL	S, M, L, XL, XXL, XXXL	Same
Flammability	Class I	Class I	Same
Hydrostatic pressure	≥50 cm	≥50 cm	Same
Water impact	≤1.0g	≤1.0g	Same
Breaking strength	MD Mean 138.64N CD Mean 75.10N	>20N	Similar
Tearing strength	MD Mean 34.39N CD Mean 18.06N	>20N	Similar
Seam strength	Mean 57.56 N	Not available on Predicate Device's 510K Summary	Similar

Evaporative Resistance	0.00315kPa • m^2/W	Not available on Predicate Device's 510K Summary	Similar
Linting	Log_{10} Mean 2.7	Log_{10}<4	Similar
Material	SMS polypropylene Nonwoven+Polyester	SMS polypropylene Nonwoven+polyester	Same
Biocompatibility			
Cytotoxicity	No cytotxicity	No cytotxicity	Same
Irritation	No Irritation	No Irritation	Same
Sensitization	No sensitization	No sensitization	Same
Sterile	Sterile/Non-sterile	Sterile/Non-sterile	Same
Sterilization method	EO sterilization	EO sterilization	Same
Ethylene Oxide Residuals	EO residual＜4mg/piece ECH residual＜9mg/piece	Not available on Predicate Device's 510K Summary	Similar

Analysis:

The subject surgical gowns are substantially equivalent to the predicate device, in terms of general intended use, performance testing, material composition, and configuration. The tearing strength, breaking strength and linting are slightly different from those of the predicate device. The proposed device has been tested according to ASTM D5587-15, ASTM D5034-09 (2017) and ISO 9073-10-2003 respectively, and met the requirements of the standard.

Under the conditions of each study, the subject surgical gowns (sterile and non-sterile) are non-cytotoxic, non-sensitizing and negligibly irritating per ISO-10993 and have met the requirements of ANSI/AAMI PB70:2012 Liquid Barrier Performance and Classification of Protective Apparel and Drapes Intended for Use in Health Care Facilities for AAMI Level 3 surgical gowns.

Evaporative Resistance: Although the data of evaporative resistance of the predicate device is not publicity available, the proposed device has been tested for the performance according to ASTM F1868-17 and the result as shown is far below the limit, i.e. 1.0 kPa • m2/W, as required by the standard, which can prove the safety and effectiveness of the proposed surgical gown.

Sterilization: Both the proposed and the predicate devices have same sterilization for sterile products, i.e. EO sterilization. Although the concrete date of EO/ECH residual of the predicate device is not publicity available, EO/ECH residual of the proposed device have been tested according to ISO 10993-7 and meet the residual requirements of the standard. No safety or effectiveness concern will be raised.

G. Summary of Non-Clinical Testing

Non-clinical tests were conducted to verify that the proposed device met all design specification. The test results demonstrated that the proposed device complies with the following standards and ANSI/AAMI PB70:2012 Liquid Barrier Performance and Classification of Protective Apparel and Drapes Intended for Use in Health Care Facilities.

- ISO 10993-5:2009 Biological Evaluation of Medical Devices - Part 5: Tests for In Vitro Cytotoxicity
- ISO 10993-7:2008 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals

- ISO 10993-10:2010 Biological Evaluation of Medical Devices - Part 10: Tests for Irritation And Skin Sensitization
- AAMI/ANSI PB70:2012, Liquid Barrier Performance and Classification of protective Apparel and Drapes Intended For Use In Health Care Facilities
- AATCC 127-2018, Water Resistance: Hydrostatic Pressure Test
- AATCC 42-2017, Water Penetration Resistance: Impact Penetration Test
- ASTM D5034-09 (2017), Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test)
- ASTM D5587-15 (2019), Standard Test Method for Tearing Strength of Fabrics by Trapezoid Procedure;
- ASTM D1683/D1683M-17(2018) Standard Test Method for Failure in Sewn Seams of Woven Fabrics
- ASTM F1868-17 Standard Test Method for Thermal and Evaporative Resistance of Clothing Materials Using a Sweating Hot Plate
- ISO 9073-10-2003 Textiles - Test methods for nonwovens - Part 10: Lint and other particles generation in the dry state
- 16 CFR 1610, Standard for the Flammability of Clothing Textiles
- ASTMF88/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;
- ASTM F1886/F1886-16 Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection

Table 3 Summary of Performance and Biocompatibility Testing

Testing Methodology	Purpose	Acceptance Criteria	Result
Performance Testing			
Hydrostatic Pressure AATCC 127-2018	To measure the resistance of a fabric to the penetration of water under hydrostatic pressure	≥50cm H_2O	**Passed** 3 non-consecutive lots tested, using a sample size of 32/lot. All parts of test specimen met the level 3 requirements.
Water Resistance AATCC 42-2017	To verify the impact penetration of the device.	≤1.0g	**Passed** 3 non-consecutive lots tested, using a sample size of 32/lot. All parts of test specimen met the level 3 requirements.
Tearing Strength ASTM D5587-15 (2019)	To determine the tearing strength of the device.	≥10N	**Passed** Sample size of 10 pcs MD Mean: 34.39N CD Mean: 18.06N

Breaking Strength ASTM D5034-09 (2017)	To determine the breaking strength and elongation of the device.	≥30N	**Passed** Sample size of 10 pcs MD Mean: 138.64N CD Mean: 75.10N
Seam Strength ASTM D1683/D1683M-17(2018)	To measure the sewn seam strength in surgical gown by applying a force perpendicular to the sewn seams	≥30N	**Passed** Sample size of 10 pcs Mean 57.56 N
Evaporative Resistance ASTM F1868-17	To measure the evaporative resistance under steady-state conditions of fabrics of the device.	≤1.0kPa·m^2/W	**Passed** Sample size of 3pcs 0.00315 kPa • m^2/W
Lint and other particles generation in the dry state ISO 9073-10-2003	To measure the linting of non-woven in the dry state.	Coefficient of linting Log_{10}≤4.0	**Passed** Sample size of 10pcs Log_{10} Mean: 2.7
Flammability 16 CFR 1610	To determine the flammability of textiles for the surgical gowns.	Class I	**Passed** Sample size of 5 pcs All samples are Class I
Biocompatibility Testing			
Cytotoxicity	Assess the potential risk of cytotoxicity of surgical gown material	Non-cytotoxic	**Passed** Under the condition of this study, the device has no potential toxicity.
Irritation	Assess the potential risk of irritation of surgical gown material	Negligibly irritating	**Passed** Under the condition of this study, the device is negligibly irritating.
Sensitization	Assess the potential risk of sensitization of surgical gown material	Non-sensitizing	**Passed** Under the conditions of the study, the device is non-sensitizing
Ethylene Oxide Residuals	Verify low levels of sterilant residuals	EO residual ＜ 4mg/piece ECH ＜9mg/piece	**Passed** The EO/ECH residuals shown in test report are far below the criteria.

H. Clinical Test Conclusion

No clinical study is included in this submission.

I. Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(K) submission,

the subject surgical gown is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K202706.