August 12, 2022

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

Re: K221027
Trade/Device Name: Isolation Gown (S, M, L, XL, XXL (Yellow, Blue))
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical apparel
Regulatory Class: Class II
Product Code: FYC
Dated: April 6, 2022
Received: April 6, 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
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)*
K221027

Device Name
Isolation Gown (S, M, L, XL, XXL (Yellow, Blue))

Indications for Use *(Describe)*
The Isolation Gowns are intended to protect health care patients and health care personnel from the transfer of microorganisms, body fluids and particulate material. Not intended for use in the operating room. In addition, The Isolation Gowns meet the requirements of an AAMI Level 3 barrier protection for an isolation gown per ANSI/AAMI PB70:2012 Liquid Barrier Performance and Classification of Protective Apparel and Drapes Intended for Use in Health Care Facilities (ANSI/AAMI PB70). The Isolation Gowns are a single use, disposable medical device provided non-sterile.

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.

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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 (K221027)

(As requirement by 21 CFR 807.92)

Date prepared: 25th, March, 2022

A. Applicant:

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B. Device:

Trade Name:Isolation Gown
Model: S, M, L, XL, XXL (Yellow, Blue)

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

C. Predicate device:

K160339
Cardinal Health™ Isolation Gown
Cardinal Health 200, LLC

D. Indications for use of the device:

The Isolation Gowns are intended to protect health care patients and health care personnel from the transfer of microorganisms, body fluids and particulate material. Not intended for use in the operating room. In addition, The Isolation Gowns meet the requirements of an AAMI Level 3 barrier protection for an isolation gown per ANSI/AAMI PB70:2012 Liquid Barrier Performance and Classification of Protective Apparel and Drapes Intended for Use in Health Care Facilities (ANSI/AAMI PB70). The Isolation Gowns are a single use, disposable medical device provided non-sterile.

E. Device Description:

The Isolation Gown is a surgical isolation gown with moderate barrier protection identified by Regulation 21 CFR 878.4040 under FDA product code, FYC. The Isolation Gown is offered in two colors (yellow and blue) and each color is offered in five sizes (S, M, L, XL and XXL) for a total of ten models. Each model is 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. The Isolation Gown is a single use, disposable medical device that will be provided in a variety of non-sterile packaging configurations.

F. Non-clinical Test Conclusion

The Isolation Gowns were tested in accordance with the tests recommended in ANSI/AAMI PB70:2012 Liquid Barrier Performance and Classification of Protective Apparel and Drapes Intended for Use in Health Care Facilities.

Based upon the document the following testing has been performed.

Test Item	Test Standard	Acceptance Criteria for Level 3 Barrier	Result of Yellow Isolation Gown XXL	Result of Blue Isolation Gown XXL
Water Resistance: Hydrostatic Pressure Test	AATCC 127-2018e	≥50 cmH_2O per standard ANSI/AAMI PB70:2012 for level 3	Passed	Passed
Water Resistance: Impact Penetration Test	AATCC 42-2017	≤1.0g AQL: 4% Level 3 per standard ANSI/AAMI PB70:2012 for level 3	Passed	Passed
Breaking Strength and Elongation	ASTM D 5034-2009 (2017)	≥30N(7lbf)	Passed	Passed
Tearing Strength	ASTM D 5587-2015	≥10N (2.3 lbf)	Passed	Passed

	(2019)			
Seam Strength	ASTM D1683/D1683M-2017 (2018)	≥30N (7lbf)	Passed	Passed
Lint and other particles generation in the dry state	ISO 9073-10:2003	Reported Data	Lint and other particles generation in the dry state[Material] Total linting: A: face 222 B: face 152 Average 187 Coefficient of linting: A: face 2.3 B: face 2.2 Average 2.3	Lint and other particles generation in the dry state[Material] Total linting: A: face 527 B: face 641 Average 584 Coefficient of linting: A: face 2.7 B: face 2.8 Average 2.8
Thermal and Evaporative Resistance	ASTM F 1868-2017	Reported Data	Evaporative resistance(m^2·kPa/W) [Material]: 0.00217	Evaporative resistance(m^2·kPa/W) [Material]: 0.00198
Flammability Test	16 CFR Part 1610	Class I	Passed	Passed
Mass Per Unit Area	ISO 9073-1:1989	Reported Data	39.56	40.62

Biocompatibility Testing

The biocompatibility evaluation for the Isolation Gown was conducted in accordance with ISO 10993-1:2018 Biological Evaluation of Medical Devices—Part 1: Evaluation and Testing within a Risk Management Process, as recognized by FDA. The Isolation Gown is classified as a surface contacting device. Specific biocompatibility tests were selected under the guidance of ISO 10993-1:2018 Annex A.

Biocompatibility Evaluation				
Biological Effect		**Standard**	**Result**	
1	Cytotoxicity	ISO 10993-5	Non-cytotoxic	Passed
2	Sensitization	ISO 10993-10	Non-sensitizing	Passed
3	Irritation	ISO 10993-10	Negligibly irritating	Passed

G. Summary of Technological Characteristics

Table 1 General Comparison of Proposed and Predicate Devices

Device	**Proposed Device**	**Predicate Device**	**Result**

510K #	-	K160339	-
Manufacturer	Allmed Medical （Hubei） Protective Products Co., Ltd	Cardinal Health 200, LLC	-
Product Name	Isolation Gown	Cardinal Health™ Isolation Gown	Similar
Level	Level 3	Level 3	Same
Product Code	FYC	FYC	Same
Regulation Number	21 CFR 878.4040	21 CFR 878.4040	Same
Indications for use	The Isolation Gowns are intended to protect health care patients and health care personnel from the transfer of microorganisms, body fluids and particulate material. Not intended for use in the operating room. In addition, The Isolation Gowns meet the requirements of an AAMI Level 3 barrier protection for an isolation gown per ANSI/AAMI PB70:2012 Liquid Barrier Performance and Classification of Protective Apparel and Drapes Intended for Use in Health Care Facilities (ANSI/AAMI PB70). The Isolation Gowns are a single use, disposable medical device provided non-sterile.	Cardinal HealthTM Isolation Gown is intended to protect health care patients and health care personnel from the transfer of microorganisms, body fluids and particulate material. Not intended for use in the operating room. In addition, The Cardinal HealthTM Isolation Gown meets the requirements of an AAMI Level 3 barrier protection for an isolation gown per ANSI/AAMI PB70:2012 Liquid Barrier Performance and Classification of Protective Apparel and Drapes Intended for Use in Health Care Facilities (ANSI/AAMI PB70).The Cardinal HealthTM Isolation Gown is a single use, disposable medical device provided non-sterile.	Same
Design Feature	Tape Neck Closure Belt Tie Elastic Cuffs	Medical Tape Neck Closure White Belt Tie Elastic Cuffs	Similar
Material Composition	Body, Sleeves and Belt:Polypropylene SMS non-woven Cuff: Polyester	Polyolefin (Polypropylene) SMS nonwoven	Similar
Color	Blue and Yellow	Blue and Yellow	Same
Sterility	Non-sterile	Non-sterile	Same
Use	Single Use, Disposable	Single Use, Disposable	Same

Table 2 Performance Comparison of Proposed and Predicate Devices

Element of Comparison	Proposed Device (Yellow)	Proposed Device (Blue)	Predicate Device (K160339) (Yellow)	Predicate Device (K160339) (Blue)	Comparison
Basis weight	39.56g/m^2 (1.17 oz/yd^2)	40.62g/m^2 (1.20 oz/yd^2)	Mean = 1.21 Ind Min = 1.19	Mean = 1.18 Ind Min = 1.15	Similar

			Ind Max = 1.23 **Unit: oz/yd²**	Ind Max = 1.20 **Unit: oz/yd²**	
Grab tensile MD ASTM D5034	Average value:88.53N (20 lbs)	Average value:139.39N (31.32 lbs)	Mean = 24.38 Ind Min = 21.94 Ind Max = 26.28 **Unit: lb**	Mean = 22.23 Ind Min = 20.42 Ind Max = 24.03 **Unit: lb**	Similar
Grab tensile CD ASTM D5034	Average value:58.05N (13.05 lbs)	Average value:77.01N (17.31 lbs)	Mean = 14.54 Ind Min = 12.70 Ind Max = 16.45 **Unit: lb**	Mean = 14.18 Ind Min = 12.40 Ind Max = 15.76 **Unit: lb**	Similar
Trap Tear MD ASTM D5587-15	Average value:24.52N (5.51 lbs)	Average value:34.42N (7.74 lbs)	Mean = 4.74 Ind Min = 3.67 Ind Max = 5.47 **Unit: lb**	Mean = 4.40 Ind Min = 3.26 Ind Max = 5.54 **Unit: lb**	Different
Trap Tear CD ASTM D5587-15	Average value:15.13N (3.4 lbs)	Average value:17.54N (3.94 lbs)	Mean = 9.24 Ind Min = 7.54 Ind Max = 12.98 **Unit: lb**	Mean = 7.99 Ind Min = 6.64 Ind Max = 11.11 **Unit: lb**	Different
Flammability Part 1610	Class I	Class I	Class I	Class I	Same
Hydrostatic Head (cm) AATCC 127	Body/Sleeve Ind Min=51.02 Ind Max=82.86	Body/Sleeve Ind Min=52.24 Ind Max=101.22	Body/Sleeve: Mean = 69 Ind Min = 56 Ind Max = 84	Body/Sleeve: Mean = 72 Ind Min = 53 Ind Max = 80	Similar
Water Impact (g) AATCC 42	Body/Sleeve: Ind Min = 0.0 Ind Max = 0.3	Body/Sleeve: Ind Min = 0.0 Ind Max = 0.3	Body/Sleeve: Mean = 0.08 Ind Min = 0.05 Ind Max = 0.13	Body/Sleeve: Mean = 0.08 Ind Min = 0.04 Ind Max = 0.13	Similar
Liquid Barrier Performance Classification Properties	Device was tested in accordance with ANSI/AAMI PB70:2012 and meets Level 3 requirements for an isolation gown. The critical zone areas tested were the the body and sleeve (same fabric), the sleeve seam, the shoulder seam, and binding material.		Device was tested in accordance with ANSI/AAMI PB70:2012 and meets Level 3 requirements for an isolation gown. The critical zone areas tested were the body and sleeve (same fabric), the sleeve seam, front belt or tie attachment, and the front seam arm attachment using multiple lots.		Similar
Biocompatibility	The test was done against ISO10993-5 and ISO10993-10. The result indicates the gown is non-cytotoxic, and non-sensitizing and negligibly irritating		Under the conditions of each study, the Cardinal HealthTM Isolation gown is non-cytotoxic, non-irritating, and non-sensitizing per ISO 10993-1.		Same
Sterilization Modality	None (Non-sterile)		None (Non-sterile)		Same

Seam Strength	Seam Strength: 58.18N Seam Strength Ultimate Elongation(%):51.04	Seam Strength:65.27N Seam Strength Ultimate Elongation(%):32.63%	Performance values not available in predicate 510(k) submission	N/A
Lint and other particles generation in the dry state	Lint and other particles generation in the dry state[Material] Total linting: A: face 222 B: face 152 Average 187 Coefficient of linting: A: face 2.3 B: face 2.2 Average 2.3	Lint and other particles generation in the dry state[Material] Total linting: A: face 527 B: face 641 Average 584 Coefficient of linting: A: face 2.7 B: face 2.8 Average 2.8	Performance values not available in predicate 510(k) submission	N/A
Thermal and Evaporative Resistance	Evaporative resistance(m^2·kPa/W) [Material]: 0.00217	Evaporative resistance(m^2·kPa/W) [Material]: 0.00198	Performance values not available in predicate 510(k) submission	N/A

Analysis:

The subject isolation gowns are substantially equivalent to the predicate device, in terms of general intended use, performance testing, material composition, and configuration. The tearing strength (both warp direction and filing direction) is slightly different from that of the predicate device. The tearing strength of the proposed device has been tested according to ASTM D5587-15 and met the requirement of the standard.

Under the conditions of each study, the subject isolation gown is 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 an AAMI Level 3 isolation gown.

H. 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 10993-05:2009 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

- 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;
- AAMI/ANSI PB70:2012, Liquid Barrier Performance and Classification of protective Apparel and Drapes Intended For Use In Health Care Facilities
- 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
- ASTM D1683/D1683M-17(2018) Standard Test Method for Failure in Sewn Seams of Woven Fabrics
- 16 CFR 1610, Standard for the Flammability of Clothing Textiles

I. Clinical Test Conclusion

No clinical study is included in this submission.

J. Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(K) submission, the subject Isolation Gown is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K160339.