June 10, 2022

Wuhan Dymex Healthcare Co., Ltd.
% Diana Hong
General Manager
Mid-Link Consulting Co.,Ltd
P.O.box 120-119
Shanghai, 200120
China

Re: K220528
Trade/Device Name: Surgical Isolation Cover Gown
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FYC
Dated: May 5, 2022
Received: May 9, 2022

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,

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

K220528

Device Name
Surgical Isolation Cover Gown

Indications for Use *(Describe)*

The Surgical Isolation Cover 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 Surgical Isolation Cover 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 Drapes Intended for Use in Health Care Facilities (ANSI/AAMI PB70). The Surgical Isolation Cover Gown is 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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510(k) Summary

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

The assigned 510(k) Number: K220528

1. Date of Preparation: 05/05/2022

2. Sponsor Identification

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3. Designated Submission Correspondent

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4. Identification of Proposed Device

Trade Name: Surgical Isolation Cover Gown
Common Name: Isolation Gown

Regulatory Information

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

Indications for Use:

The Surgical Isolation Cover 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 Surgical Isolation Cover 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 Drapes Intended for Use in Health Care Facilities (ANSI/AAMI PB70). The Surgical Isolation Cover Gown is a single use, disposable medical device provided non-sterile.

Device Description:

The proposed device 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. The proposed device is a single use, disposable medical device provided non-sterile.

The proposed device is available in nine sizes, including XS, S, M, L, XL, 2XL, 3XL, 4XL, 5XL. The barrier protection level for Surgical Isolation Cover Gown meets AAMI Level 3. The proposed device is provided in yellow.

5. Identification of Predicate Device

510(k) Number: K171535
Product Name: Surgical Isolation Gown

6. Summary of Technological characteristics

Table 1 General Comparison

Item	Proposed Device	Predicate Device K171535	Remark
Product Code	FYC	FYC	Same
Regulation No.	21CFR 878.4040	21CFR 878.4040	Same
Class	II	II	Same
Indications for Use	The Surgical Isolation Cover 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 Surgical Isolation Cover 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 Drapes Intended for Use in Health Care Facilities (ANSI/AAMI PB70). The Surgical Isolation Cover Gown is a single use, disposable medical device provided non-sterile.	The Surgical 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 Surgical 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 Drapes Intended for Use in Health Care Facilities (ANSI/AAMI PB70). The Surgical Isolation Gown is a single use, disposable medical device provided non-sterile.	Same
Design	Neck Closure Yellow Belt Tie Elastic Cuffs	Medical Tape Neck Closure White Belt Tie Snap fastener	Similar
Use	Single Use, Disposable	Single Use, Disposable	Same
Color	Yellow	Yellow	Same
Labeling	Conform with 21CFR Part 801	Conform with 21CFR Part 801	Same

Table 2 Safety and Effectiveness Comparison

Item	Proposed Device	Reference Device K171535	Remark
Weight per square	35 g/m^2	Testing not performed	Different
Size	XS, S, M, L, XL,2XL,3XL,4XL,5XL	U, XL, 2XL	Different
Flammability	Class I	Class I	Same

Hydrostatic Pressure (cm H_2O)		Mean = 70.63 Max = 72.33 Min = 68.88	CHEST/BACK/SLEEVE: Mean = 69 Ind Min = 54 Ind Max = 84	Different
Water impact (g)		Mean = 0.58 Max = 0.69 Min = 0.49	Sleeve Seams: Mean = 0.04 Ind Min = 0.02 Ind Max = 0.08 CHEST: Mean = 0.04 Ind Min = 0.02 Ind Max = 0.05 Back: Mean = 0.05 Ind Min = 0.04 Ind Max = 0.07	Different
Breaking strength	MD	Mean = 74.82 N Max = 79.64 N Min = 70.43 N	Mean = 20.71 lbs (92.16 N) Ind Min = 19.73 lbs (87.80 N) Ind Max = 21.87 lbs (97.32 N)	Different
	CD	Mean = 49.35 N Max = 55.18 N Min = 40.96 N	Mean = 12.21 lbs (54.33 N) Ind Min = 11.20 lbs (49.84 N) Ind Max = 14.11 lbs (62.79 N)	
Tearing strength	MD	Mean = 62.92 N Max = 69.72 N Min = 62.01 N	Mean = 3.48 lbs (15.49 N) Ind Min = 2.82 lbs (12.55 N) Ind Max = 3.93 lbs (17.49 N)	Different
	CD	Mean = 32.57 N Max = 34.99 N Min = 30.05 N	Mean = 7.15 (31.82 N) Ind Min = 6.20 (27.59 N) Ind Max = 7.70 (34.27 N)	
Linting		Side A: Log_{10}(lint count): Mean 3.4 Side B: Log_{10}(lint count): Mean 3.4	SIDE A: OUTSIDE TOTAL >0.3 1024 TOTAL >0.5 658 SIDE B: INSIDE TOTAL >0.3 1066 TOTAL >0.5 697	Different
Seam strength		Mean = 102.92 N Max = 109.98 N Min = 95.37 N	/	Different
Air permeability		Mean 35.4 $ft^3/min/ft^2$	/	Different
Barrier protection level		Level 3 per AAMI PB 70	Level 3 per AAMI PB 70	Same

Material	SMS Nonwoven Fabric	Polypropylene SMS non woven	Same
Biocompatibility			
Cytotoxicity	The test was done against ISO10993-5 and ISO10993-10. The result indicates the gown is noncytotoxic, non-irritating, and non-sensitizing per ISO 10993-1.	The test was done against ISO10993-5 and ISO10993-10. The result indicates the gown is noncytotoxic, non-irritating, and non-sensitizing per ISO 10993-1.	Same
Irritation			
Sensitization			
Sterilization	Non-sterile	Non-sterile	Same

Similar - Design

The design of the proposed device is not exactly the same as the predicate device. The belt tie of the proposed device is yellow, while the belt tie of the predicate device is white. However, the belt tie is used to close the back of the gown. The difference in the color of belt tie will not affect the device performance.

Different - Weight per square

No information was available on the Weight per square of the predicate device. The weight per square for the proposed device is 35g/m^2, which is similar to the most products on the market. And the difference in the weight per square will not affect the intended use. In addition, the performance testing was conducted on the proposed device and the results demonstrate that the proposed device can meet the barrier protection level 3 requirement as required by PB70.

Different - Size

The size for the proposed device is different from the predicate device. The proposed device is available in nine size, including XS, S, M, L, XL,2XL,3XL,4XL,5XL, while the predicate device is available in three size, U, XL and 2XL. However, the difference in the size will not affect the device performance. Different sizes can be selected by surgeon's condition.

Different - Hydrostatic pressure

The hydrostatic pressure for the proposed device is different from the predicate device. the higher the hydrostatic pressure value, the higher the protection of the isolation gown. The hydrostatic pressure of the proposed device is 70.63 cm H_2O, which is greater than the 69 cm H_2O of the predicate device.

Different - Water impact

The water impact for the proposed device is different from the predicate device. However, the water in impact test was conducted on the proposed device and the results demonstrate that the proposed device meets the barrier protection level 3 requirement, i.e., no more than 1.0g, as required by PB70.

Different - Breaking strength

The breaking strength for the proposed device is different from the predicate device. Although the MD and CD breaking strength of the proposed device is smaller than the predicate device, the MD and CD breaking strength of the proposed device meets ASTM F2407-20's requirement of greater than 30N.

Different - Tearing strength
The tearing strength for the proposed device is different from the predicate device. Tearing strength is one of the indicators to evaluate the ability of the isolation gown to withstand destructive force. The greater the tearing strength value, the stronger the ability to withstand destructive force. The tearing strength of the proposed device is larger than the predicate device.

Different - Linting
The linting for the proposed device is different from the predicate device. However, the linting test was conducted on the proposed device and the testing results demonstrate that the proposed device can meet the requirements of log10<4.

Different - Seam strength
The seam strength was conducted on the proposed device and the testing results demonstrate that the seam strength of the proposed device meets ASTM F2407-20's requirement of greater than 30N.

Different - Air permeability
The air permeability was conducted on the proposed device and the testing results demonstrate that the air permeability of the proposed device meets the requirement of greater than 30 $ft^3/min/ft^2$.

7. Summary of Non-Clinical Tests

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

- 16 CFR Part 1610 Standard for the Flammability of Clothing Textiles;
- AATCC 127: 2018 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(2018) Standard Test Method for Failure in Sewn Seams of Woven Fabrics;
- ASTM D5587: 2015(2019) Standard Test Method for Tearing Strength of Fabrics by Trapezoid Procedure;
- ASTM D5034: 2009(2017) Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test);

- 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;
- ASTM D737-18: 2018 Standard Test Method for Air Permeability of Textile Fabrics

Table 3 Summary of Performance Testing

Test Methodology	Purpose	Acceptance Criteria	Result
Flammability	The test was performed in accordance with 16 CFR Part 1610 Standard for the Flammability of Clothing Textiles to evaluate the flammability of the test sample.	Meets Class 1 requirements	Class 1
Hydrostatic pressure	The test was performed in accordance with AATCC 127: 2017 Water Resistance: Hydrostatic Pressure Test to determine the hydrostatic pressure of the test sample.	>50 cm H_2O	Mean = 70.63 cm H_2O Max = 72.33 cm H_2O Min = 68.88 cm H_2O
Water impact	The test was performed in accordance with AATCC 127: 2017 Water Resistance: Hydrostatic Pressure Test to determine the hydrostatic pressure of the test sample.	≤1.0 g	Mean = 0.58 g Max = 0.69 g Min = 0.49 g
Breaking strength	The test was performed in accordance with ASTM D 5034:2009(2017) Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test) to evaluate the breaking strength of the test sample.	>20 N	MD: Mean = 74.82 N Max = 79.64 N Min = 70.43 N CD: Mean = 49.35 N Max = 55.18 N Min = 40.96 N
Tearing strength	The test was performed in accordance with ASTM D5587:2015(2019) Standard Test Method for Tearing Strength of Fabrics by Trapezoid Procedure to evaluate the tearing strength of the test sample.	>20 N	MD: Mean = 62.92 N Max = 69.72 N Min = 62.01 N CD: Mean = 32.57 N Max = 34.99 N Min = 30.05 N

Linting	The test was performed in accordance with ISO 9073-10:2003 Textiles-Test Methods for Nonwovens-Pat 10: Lint and Other Particles Generation in the Dry State to evaluate the linting of the test sample.	Log10(particle count) < 4	Side A: Log_{10}(lint count): Mean 3.4 Side B: Log_{10}(lint count): Mean 3.4
Seam strength	The test was performed in accordance with ASTM D1683/D1683M: 2017(2018) Standard Test Method for Failure in Sewn Seams of Woven Fabrics to evaluate the seam strength of the test sample.	>50 N	Mean = 102.92 N Max = 109.98 N Min = 95.37 N
Air permeability	The test was performed in accordance with ASTM D737: 2018 Standard Test Method for Air Permeability of Textile Fabrics to evaluate the air permeability of the test sample.	>30 $ft^3/min/ft^2$	Mean 35.4 $ft^3/min/ft^2$

Table 4 Summary of Biocompatibility Testing

Test Methodology	Purpose	Acceptance Criteria	Result
Cytotoxicity	The test was performed in accordance with ISO 10993-5 Third edition 2009-06-01 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity to evaluate the cytotoxicity of the test sample.	The viability should be ≥ 70% of the blank. And the 50% extract of the test sample should have at least the same or a higher viability than the 100% extract.	The viability was ≥70% of the blank. And the 50% extract of the test sample had a higher viability than the 100% extract. Under the conditions of the study, the proposed device was non-cytotoxic.
Sensitization	The test was performed in accordance with ISO 10993-10 Third Edition 2010-08-01 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization to evaluate the sensitization of the test sample.	Non-sensitizing	Under the conditions of the study, the proposed device was non-sensitizing.

Irritation	The test was performed in accordance with ISO 10993-10 Third Edition 2010-08-01 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization to evaluate the irritation of the test sample.	Non-irritating	Under the conditions of the study, the proposed device was non-irritating.

8. Clinical Test Conclusion

No clinical study is included in this submission.

9. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the proposed devices are as safe, as effective, and perform as well as or better than the legally marketed predicate device K171535.