August 21, 2021

Anhui Medpurest Medical Technology Co.,Ltd
% Ivy Wang
Technical Manager
Shanghai Sungo Management Consulting Company Limited
13th Floor, 1500# Central Avenue
Shanghai, Shanghai 200122
China

Re: K202532
Trade/Device Name: Disposable Surgical Gowns
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FYA
Dated: July 15, 2021
Received: August 11, 2021

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202532

Device Name
Disposable Surgical Gowns

Indications for Use *(Describe)*
Disposable Surgical Gowns are intended to be worn by operating room personnel during surgical procedures to protect the surgical patient and operating room personnel from the transfer of microorganisms, body fluids and particulate material. This surgical gown meets the requirements of AAMI Level 3 barrier protection for a surgical gown per ANSI/AAMI PB70:2012 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities (AAMI PB70).

The Surgical Gowns are single use, disposable medical devices; provided sterile or non-sterile. 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 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.

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510(K) Summary

Document prepared date: 8/21/2021

A. Applicant:

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B. Device:

Trade Name: Disposable Surgical
Gowns Common Name: Surgical
Gown Model(s): MDSG-1052

Regulatory Information
Classification Name: Gown,
Surgical Classification:
Class II Product code: FYA
Regulation Number:
878.4040 Review Panel:
Surgical Apparel

C. Predicate device:

K170762
Cardinal Health™ Non-Reinforced Surgical
Gown Cardinal Health 200, LLC

D. Intended use of the device:

Disposable Surgical Gowns are intended to be worn by operating room personnel during

surgical procedures to protect the surgical patient and operating room personnel from the transfer of microorganisms, body fluids and particulate material. This surgical gown meets the requirements of AAMI Level 3 barrier protection for a surgical gown per ANSI/AAMI PB70:2012 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities (AAMI PB70). The Surgical Gowns are single use, disposable medical devices; provided sterile or non-sterile. 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 users after EtO sterilization validation to ISO 11135-1.

E. Device Description:

Surgical Gown is designed for the medical personnel using in operation. The employed material is SMS compound non-woven fabric. The material has many good properties，such as soft，clean，good filtration and uniformity and waterproof， they are not sensitive to human beings， difficult to fluff， they don't have any peculiar smell， other matters and primary color. The gowns are for safe use in the operating room environment, i.e., lint free, free of toxic ingredients and non-fast dyes. It is a kind of Non- Reinforced surgical gown.

The chest front and sleeve critical zones of the Disposable Surgical Gowns are constructed from a blue polyolefin SMS (spunbond, meltblown, spunbond) and have been tested according to AAMI PB70:2012 and meet AAMI Level 3 barrier level protection for a surgical gown. The Disposable Surgical Gown is a single use, disposable medical device that will be provided in a variety of nonsterile packaging configurations.

F. Technological Characteristic Comparison

Device	**Proposed Device**	**Predicate Device**	**Result**
Manufacturer	Anhui Medpurest Medical Technology Co.,Ltd	Cardinal Health™	-
510K number	K202532	K170762	-
Model Name	Disposable Surgical Gowns	Cardinal Health™ Non-Reinforced Surgical Gown	-
Classification	Class II Device, FYA (21 CFR878.4040)	Class II Device, FYA (21 CFR878.4040)	Same

Intend use	Disposable Surgical Gowns are intended to be worn by operating room personnel during surgical procedures to protect the surgical patient and operating room personnel from the transfer of microorganisms, body fluids and particulate material. This surgical gown meets the requirements of AAMI Level 3 barrier protection for a surgical	Cardinal Health™ Non-Reinforced Surgical Gown is intended to be worn by operating room personnel during surgical procedures to protect the surgical patient and operating room personnel from the transfer of microorganisms, body fluids and particulate material. In addition, this surgical gown meets the requirements of AAMI Level 3 barrier protection for a surgical gown	Same

	gown per ANSI/AAMI PB70:2012 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities (AAMI PB70). The Surgical Gowns are single use, disposable medical devices; provided sterile or non-sterile. 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 users after EtO sterilization validation to ISO 11135-1.	per ANSI/AAMI PB70:2012 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities (AAMI PB70). The Cardinal Health™ Non-Reinforced Surgical Gowns are single use, disposable medical devices; provided sterile and non-sterile.	
Material Composition	Polyolefin (Polypropylene) SMS nonwoven	Polyolefin (Polypropylene) SMS nonwoven	Same
Sterility	Non-Sterile	Sterile and Non-sterile	Same
Use	Single Use; Disposable	Single Use; Disposable	Same
Color	Blue	Blue	Same
Size	S,M,L,XL,XXL	M-S, M, L, XL, XXL	Same
Weight per square(g)	45 g/m^2	31g/m^2 (1.32 oz/yd2)	Similar
Tensile	MD Mean 123.4N CD Mean 88.2N	MD Mean 21.57 lbs CD Mean 13.6 lbs	Similar
Tear	MD Mean 60.4N CD Mean 40.2N	MD Mean 3.47 lbs CD Mean 5.63 lbs	Similar
Hydrostatic Pressure(cm) AATCC-127	>50 cm	>50 cm	Same
Water Impact (g) AATCC-42	≤1.0 g	≤1.0 g	Same
Level	Level 3	Level 3	Same
Resistance to blood and liquid penetration	Level 3 AAMI PB70	Level 3 AAMI PB70	Same

EtO/ECH Residuals	Device is naturally degassing for 48 hours, both EtO and ECH residuals below the detection limit(0.03μg/g)	No available on Predicate Device's 510(k) Summary	Similar
Shelf-life	3 years	No available on Predicate Device's 510(k) Summary	Similar
Biocompatibility	Under the conditions of the study, the device extract was not cytotoxic. Under the conditions of the study, the non-polar and polar device extracts were not found to be an irritant. Under conditions of the study, the non-polar and polar device extracts were not found to be a sensitizer.		Same

G. Non-Clinical Test Conclusion

Non-clinical tests were conducted to verify that the proposed device met all design specifications. The test results demonstrated that the proposed device met its acceptance criteria or testing endpoint safe levels using the following standards:

- 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
- CPSC 16 CFR Part 1610-2008, Standard for the Flammability of clothing textiles;
- AATCC 127-2014, Water Resistance: Hydrostatic Pressure Test;
- AATCC 42-2013, Water Penetration Resistance: Impact Penetration Test;
- ASTM D5034-09, Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test);
- ASTM D5587-15, 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.

Table 2 - Performance Testing

Testing Methodology	Purpose	Acceptance Criteria	Results
Hydrostatic Pressure AATCC127:2014	The purpose of the performance testing is to demonstrate the functionality of the subject device.	≥50cm H_2O	**PASS** 3 non-consecutive lots tested, using a sample size of 32/lot.
			Average of 203cm on Front body material, 168cm on back body material and 60cm on seam.

Water-proof Property AATCC42:2013		≤1.0g	**PASS** 3 non-consecutive lots tested, using a sample size of 32/lot. 0g on Critical Zone (Body material, Sleeve seam and Adhesive part of belt)
Tear strength(N) Trapezoid Method ASTM D 5587-2015,		MD/CD≥ 10N	**PASS** Sample size of 5 pcs
			MD Mean 60.4N CD Mean 40.2N
Breaking Strength ASTM D 5034-2009(2017)		MD/CD≥ 30N	**PASS** Sample size of 8 pcs CD Mean 88.2N
Sewn seam strength (sleeve seam) ASTM D1683/D1683M-2017(2018)		Seam Strength ≥ 30N	**PASS** Sample size of 5 pcs Seam Strength Mean: 64.5 N
Water-vapor resistance ASTM F 1868-2017		≤3.0 $Pa \cdot m^2/W$	**PASS** Sample size of 3 pcs
			Water-vapor resistance Mean: 2.42 $Pa \cdot m^2/W$
Lint and other particles generation in the dry state ISO 9073-10: 2003		Coefficient of linting $Log_{10} \leq 4.0$	**PASS** Sample size of 5 pcs Log_{10} Mean: 3
Mass per unit area ASTM D3776/D3776M-2009(2017)		N/A	Sample size of 5 pcs. Mass per unit area Mean: 45 g/m^2
Burning Behavior 16 CFR Part 1610		Class I	**PASS** Sample size of 5 pcs Class I

Table 3 Biocompatibility Testing

Item	Purpose	Acceptance Criteria	Result

Cytotoxicity	The purpose of the biocompatibility testing is to demonstrate the biocompatibility of the subject device.	Non-Cytotoxic	**PASS** Under the conditions of the study, the device is non-cytotoxic.
Irritation		Non-Irritating	**PASS** Under the conditions of the study, the device is non-irritating.
Sensitization		Non-Sensitizing	**PASS** Under the conditions of the study, the device is non-sensitizing

H. Clinical Test Conclusion

No clinical study is included in this submission.

I. Conclusion

Based on the nonclinical tests performed, the subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate device, Disposable Surgical Gowns cleared under K170762.