May 5, 2025

Dae Myung Chemical Co., Ltd. (vietnam)
Tri Do Minh
QA Manager
Lot CI.II-7a and Lot CI.II-7a', Street No. 5,
Long Thanh Industrial Zone, Tam An Ward
Long Thanh, Dong Nai 810000
Vietnam

Re: K242937
Trade/Device Name: Dream Medi Sterile Surgical Gown (SurgicalGownUL)
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FYA
Dated: June 14, 2024
Received: March 31, 2025

Dear Tri Do Minh:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

Bifeng Qian, M.D., Ph.D.
Assistant Director
DHT4C: Division of Infection Control 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K242937

Device Name
Dream Medi Sterile Surgical Gown (SurgicalGownUL)

Indications for Use *(Describe)*
The Dream Medi Sterile 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 matter.
In addition, this surgical gown meets the requirements of AAMI Level 3 barrier protection for a surgical gown per ANSI/AAMI PB70 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities (AAMI PB70). This is a single use, disposable device, provided 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary K242937

(As required by 21 CFR 807.92)

1.0 Submitter's information

Name: DAE MYUNG CHEMICAL CO., LTD. (VIETNAM)
Address: Lot CI.II-7a and Lot CI.II-7a', Street No. 5, Long Thanh Industrial Zone, Tam An Ward, Long Thanh Dong Nai 810000 Vietnam
Contac: Mr. Tri Do Minh
Phone Number: +84 251-3514 017
Email: qc.tri@dmpoly.com
Date of Preparation: April 04, 2025

2.0 Device information

Trade name: Dream Medi Sterile Surgical Gown (SurgicalGownUL)
Common name: Surgical Gown
Classification name: Gown, Surgical
Model: SurgicalGownUL
Size: S, M, L, XL, XXL

3.0 Classification

Production code: FYA - Gown, Surgical
Regulation number: 21CFR 878.4040 - Surgical apparel
Classification: Class II
Panel: Surgical apparel

4.0 Predicate device information

Name: Hubei Woozon Healthcare Co.,Ltd.
Address: Nongfeng Road, Nonwoven Fabric Industrial Park, Wangzhou Avenue, Pengchang Town, Xiantao City, Hubei, China
K number: K222999

5.0 Intended Use/Indication for Use Statement

The Dream Medi Sterile 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 matter.
In addition, this surgical gown meets the requirements of AAMI Level 3 barrier protection for a surgical gown per ANSI/AAMI PB70 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities (AAMI PB70). This is a single use, disposable device, provided sterile.

6.0 Device description

Dream Medi Surgical Gowns are made from SMS material. They are full length, constructed with raglan sleeves, hook and loop neck closures, and tie waist closures. They provide AAMI Level-3 protection.
The Level 3 Gowns have five different sizes: Small (S), Medium (M), Large (L), Extra Large (XL), Extra Extra Large (XXL).
SMS is a multi-ply material consisting of layers of spunbond and meltblown polypropylene.

The body is made from 44g Blue SMS and the sleeve is made from 54g Blue SMS. Sleeve opening is made from pure polyester. The collar closure is made from dacron. All gowns are sterilized with ethylene oxide.

7.0 Technological Characteristic Comparison Table

Table - General Comparison

Feature	Dream Medi Sterile Surgical Gown	Predicate (K222999)	Comparison
Regulatory Classification	Class II	Class II	Same
Regulation Number	21 CFR 878.4040	21 CFR 878.4040	Same
Product Code	FYA	FYA	Same
Device Name	Surgical Gown	Surgical Gown	Same
Models	S, M, L, XL, XXL	S, M, L, XL, XXL	Same
Intended Use	**Dream Medi Sterile 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. 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). **Dream Medi Sterile Surgical Gown** are single use, disposable medical devices; the Surgical Gowns were sterilized by EO sterilization based on ISO 11135:2014	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 non-sterile. Before the use, the Surgical Gowns must be sterilized by EO sterilization based on ISO 11135:2014.	Same
Material	SMS Nonwoven Fabric	SMS Nonwoven Fabric	Same
Color	Blue	Blue	Same
Sterility	Sterile (by EO sterilization)	Sterile (by EO sterilization)	Same
Single Use	Yes	Yes	Same
AAMI Barrier Level	Level 3	Level 3	Same
Impact Penetration (AATCC 42)	≤1.0 g	≤1.0 g	Same
Hydrostatic Resistance (AATCC	≥50 cm	≥50 cm	Similar

127)			
Tensile Strength (ASTM D5034)	Machine Direction Wet: 115.44 N (25.9 lbf) Machine Direction Dry: 114.62 N (25.7 lbf)	Machine Direction Mean: 32.9 lbf Cross Direction Mean: 26.3 lbf Cross Direction Wet: 88.5 N (19.89 lbf) Cross Direction Dry: 94.66 N (21.28 lbf)	Similar
Tear Resistance (ASTM D5587)	Machine Direction Mean: 22.59 N Cross Direction Mean: 15.14 N	Machine Direction Mean: 9.3 lbf Cross Direction Mean: 18.2 lbf	Similar
Seam Strength (ASTM D1683)	Mean 67.17 N	Shoulder: 48.7N Armhole: 33.9N Sleeve: 49.6N	Similar
Flammability (16 CFR Part 1610)	Ignited but self-extinguished (Class 1)	Class 1, Non Flammable	Same
Lint Generation (ISO 9073-10)	Log10 < 4	Log10 < 4	Same
Cytotoxicity	No potential cytotoxicity	No potential cytotoxicity	Same
Irritation	No irritation	No irritation	Same
Sensitization	No sensitization	No sensitization	Same
Acute Systemic Toxicity	Not performed	No acute systemic toxicity in vivo	Different(Acute Systemic toxicity not required if Cytotoxicity passed.)
Sterilization Method	Ethylene Oxide (EO)	Ethylene Oxide (EO)	Similar
Shelf life	03 years	03 years	Same

8.0 Summary of Non-Clinical Testing

Non-clinical testing was performed to confirm that the proposed device met all design specifications. The performance of the subject surgical gown was evaluated using established standards and test methods in accordance with FDA-recognized consensus standards and applicable guidance documents to ensure compliance with safety and performance requirements.

The test results demonstrated that the proposed device met its acceptance criteria or testing endpoints

Purpose	Test	Acceptance Criteria	Results
Impact Penetration	AATCC 42	Level 3, ≤1.0 g	Pass

Hydrostatic Resistance	AATCC 127	Level 3, ≥50 cm	Pass
Tensile strength	ASTM D5034	≥30 N (≥ 7 lbf)	Pass
Tear resistance	ASTM D5587	≥10 N (≥ 2.3 lbf)	Pass
Seam strength	ASTM D1683	≥30 N (≥ 7 lbf)	Pass
Lint and Other particles generation in the dry state	ISO 9073-10	Log 10 < 4	Pass
Flammability testing	16 CFR Part 1610	Class 1	Pass
Biocompatibility cytotoxicity	ISO 10993-5	Non-cytotoxic	Pass
Biocompatibility irritation	ISO 10993-23	Non-irritant	Pass
Biocompatibility Sensitization	ISO 10993-10	Non-sensitizing	Pass

9.0 Summary of Clinical Testing

No clinical study was conducted.

10.0 Conclusion

The conclusion drawn from the non-clinical tests demonstrates that the subject device, the Dream Medi Sterile Surgical Gown, is as safe, as effective, and performs as well as or better than the legally marketed predicate device K222999.