December 17, 2021

Dong Nai Garment Corporation (Donagamex)
Bari Steinberg
Official Correspondent for Dong Nai Garment Corporation (Donagamex)
mdi Consultants, Inc.
55 Northern Blvd., Suite 200
Great Neck, New York 11021

Re: K203821
Trade/Device Name: Donagamex Blue Performance Surgical Gown
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: QPC
Dated: August 29, 2021
Received: September 7, 2021

Dear Bari Steinberg:

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,

For Clarence W. Murray, III, 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)*
K203821

Device Name
Donagamex Blue Performance Protective Gown

Indications for Use *(Describe)*
Donagamex protective gowns are non-sterile, single use surgical apparel intended to be worn by healthcare personnel to help protect both the patient and the healthcare worker from the transfer of microorganisms, body fluids, and particulate matter.

The Donagamex protective gowns meet the requirements of AAMI Level 3 barrier protection for a protective gown per ANSI/AAMI PB70: 2012 Liquid Barrier Performance and Classification of protective apparel and drapes intended for use in healthcare facilities (AAMI PB70).

The Donagamex protective gowns are sold non-sterile, single use. They are not intended for use in the operating room.

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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510(K) SUMMARY

The assigned 510(k) number is: K203821

Date Summary Prepared: December 17, 2021

1. **Submitter's Identification:**

Dong Nai Garment Corporation
Road 2, Bien Hoa Industrial Zone 1
An Binh Ward, Bien Hoa City
Dong Nai Province, Vietnam
Tel.: +84 0253 836147
Fax: +84 0253 836151

Official Correspondent: Bari Steinberg, mdi Consultants Inc.
E-mail: bari@mdiconsultants.com

2. **Device Name:** Donagamex Blue Performance Protective Gown

3. **Regulatory Information:**

Regulation Number: 21 CFR 878.4040
Device Class: Class II
Regulation Name: Surgical Apparel
Product Code: QPC
Common Name: Gown, Non-Sterile, Non-Isolation

4. **Predicate Device Information:**

510K Number: K160337
Device Name: ValueCare Open Back Protective Gown

5. **Intended Use:**

Donagamex protective gowns are non-sterile, single use surgical apparel intended to be worn by healthcare personnel to help protect both the patient and the healthcare worker from the transfer of microorganisms, body fluids, and particulate matter.

The Donagamex protective gowns meet the requirements of AAMI Level 3 barrier protection for a protective gown per ANSI/AAMI PB70: 2012 Liquid Barrier Performance and Classification of protective apparel and drapes intended for use in healthcare facilities (AAMI PB70).

The Donagamex protective gowns are sold non-sterile, single use. They are not intended for use in the operating room.

6. Device Description:

The Donagamex Blue Performance Protective Gown is a Class II medical device under the FDA product code QPC, General & Plastic Surgery Panel, and Regulation 21 CFR 878.4040. The device description of the Donagamex Blue Performance Protective Gown is in accordance with the *Guidance on Premarket Notification [510(k)] Submissions for Surgical Gowns and Surgical Drapes*, issued on August 1, 1993. The Donagamex Blue Performance Protective Gowns are non-woven, blue gowns, available in various sizes and have no areas of reinforcement. They are made from a layer of polyethylene laminated over spun-bonded polypropylene and have been tested according to AAMI PB70:2012 and meet AAMI Level 3 barrier level protection for a protective gown. The Donagamex Blue Performance Protective Gown is a single use, disposable medical device that will be sold non-sterile.

7. Device and Predicate Device Technical Characteristics:

Table 1: Side by Side Comparison

COMPARISON CRITERIA	SUBJECT DEVICE (K203821)	PREDICATE DEVICE (K160337)	COMPARISON RESULT
Device Name	Donagamex Blue Performance Protective Gown (AAMI Barrier Level 3)	ValueCare Open Back Protective Gowns (AAMI Barrier Level 3)	N/A
Manufacturer	Dong Nai Garment Corporation (Donagamex)	ValueCare	N/A
Classification	Surgical Apparel 21 CFR Part 878.4040 Product Code: QPC Class II	Surgical Apparel 21 CFR Part 878.4040 Product Code: QPC Class II	Same
Indications for Use	Donagamex Blue Performance Protective Gowns are non-sterile, single use surgical apparel intended to be worn by healthcare professionals to help protect both the patient and the health care personnel from the transfer of microorganisms, body fluids, and particulate matter. The Donagamex Protective gown meets the requirements of AAMI Level 3 barrier protection for a protective gown per	These gowns are intended to protect health care patients and health care personnel from the transfer of micro- organisms, body fluids and particulate material. The back of the gown is open and non-protective. They are not intended for use in the operating room.	Similar

	ANSI/AAMI PB70: 2012 Liquid Barrier Performance and Classification of protective apparel and drapes intended for use in healthcare facilities (AAMI PB70). The Donagamex protective gowns are sold non-sterile, single use. They are not intended for use in the operating room.		
Sterile or Non-Sterile	Non-Sterile	Non-sterile	Same
Reusable or Disposable (Single Use)	Single use	Single use	Same
Design	Elastic at the cuff for keeping the sleeves in place on the wearer, belt tie	Design includes open back, thumb loops, back perforation for easy removal and waist tie	Similar
Material Composition	Nonwoven polypropylene spunbond fabric with polyethylene laminate film (SF)	Made from extruded plastic film	Similar
Size	Medium to XX-Large	Not reported in 510k Summary	N/A
Color	Blue	Blue	Same
Sterilization Method (if applicable)	None, non-sterile gowns	None, non-sterile gowns	Similar
Packaging	Bulk for non-sterile gowns	Not reported in 510k Summary	N/A
Natural rubber Latex	Not made with natural rubber latex	Not made with Natural Rubber Latex	Same
PERFORMANCE TEST RESULTS :			
AATCC 42 Water Resistance: Impact Penetration (g)	Meets AAMI PB70 Barrier Classification for Level 3	Meets AAMI PB70 Barrier Classification for Level 3 in critical zones	Same
AATCC 127 Water Resistance: Hydrostatic Pressure (cm)	Meets AAMI PB70 Barrier Classification for Level 3	Meets AAMI PB70 Barrier Classification for Level 3 in critical zones	Same

Liquid Barrier Performance Classification	Device was tested in accordance with AAMI PB 70:2012 and meets AAMI Level 3 barrier protection requirements for a protective gown. Testing was performed using 3 nonconsecutive lots and 32 samples per lot in each critical zone area. The critical zone areas tested were the chest, back and sleeve seam.	Device meets the barrier protection requirements of AAMI Level 3 per *ANSI/AAMI PB70:2012*, but has an open back which is non-protective.	Similar
ASTM - D3776 Standard Test Methods for Mass Per Unit Area (Weight) of Fabric	Pass	Not reported in 510k Summary	N/A
ASTM - D5034 Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test)	Pass	Not reported in 510k Summary	N/A
ASTM - D5587 Standard Test Method for Tearing Strength of Fabrics by Trapezoid Procedure	Pass	Not reported in 510k Summary	N/A
ASTM - D751 Standard Test Methods for Coated Fabrics (Seam Strength)	Pass	Not reported in 510k Summary	N/A
Flammability Test Method Standard for Flammability of Clothing Textiles (16 CFR Part 1610)	Meets Class I Flammability per CPSC, Part 1610	Meets Class I Flammability per CPSC, Part 1610	Same
Textiles ISO 9073-10 Test Method for Nonwovens Part 10: Lint & other	Pass	Not reported in 510k Summary	N/A

Particles Generation in the Dry State			
ISO 10993 Part-1 Biological Evaluation of Medical Devices. Biocompatibility tests included cytotoxicity, sensitization and irritation.	Non-cytotoxic, non-sensitizing, non-irritating	Non-cytotoxic, non-sensitizing, non-irritating	Same

Both gowns are disposable, single use, non-reinforced gowns intended to help protect from the transfer of body fluids and particulate matter in settings other than the operating room. They are similar in color, design and are both offered as non-sterile.

The primary difference is that the ValueCare Open Back Protective Gown provides liquid barrier protection in front of gown only (critical zones), while the Donagamex Blue Performance Protective Gowns provide AAMI Level 3 in front and back of gown.

The above differences in design and AAMI liquid protection level raise no new issues of safety and effectiveness since both gowns are designed, tested, and labeled in compliance with the applicable AAMI PB70: 2012 liquid barrier requirements.

8. Summary of Clinical Testing:

Clinical performance for non-sterile, disposable protective gowns is not applicable for this product. Numerous predicated devices (gowns) exist and have been used extensively for a number of years that are made from the same or similar materials.

9. Summary of Non-Clinical Performance Testing:

The information in the Premarket Notification on safety and effectiveness supports a finding of substantial equivalence to devices already in commercial distribution. Equivalence is demonstrated through intended use, materials, design test methods including physical, mechanical, liquid barrier and biocompatibility testing. The Donagamex Blue Performance Protective Gown was found to be acceptable for its intended use in each of these applicable industry recognized standards:

AATCC 42:2017 Standard Test Method for Water Resistance: Impact Penetration

AATCC 127:2018 Standard Test Method for Water Resistance: Hydrostatic Pressure

ASTM - D5034:2017 Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test)
ASTM - D5587:2019 Standard Test Method for Tearing Strength of Fabrics by Trapezoid Procedure

ASTM - D751:2019 Standard Test Methods for Coated Fabrics

ASTM - D3776:2020 Standard Test Methods for Mass Per Unit Area (Weight) of Fabric

16 CFR Part 1610 - Flammability Test Method Standard for Flammability of Clothing Textiles

ISO 9073-10 Textiles - Test Method for Nonwovens Part 10: Lint & other Particles Generation in the Dry State

AMMI /ANSI / ISO 10993-5:2009 – In Vitro Cytotoxicity using Agar Overlay test (USP, ISO)

AAMI / ANSI / ISO 10993-10:2010 – In Vitro Irritation reactivity using Primary Skin Irritation Test

AAMI / ANSI / ISO 10993-10:2010 – In Vitro Sensitization using the Buehler Method Test

Table 2: Non-Clinical Tests

Test Method	Purpose	Acceptance Criteria	Results
AATCC 42:2017 Standard Test Method for Water Resistance: Impact Penetration	Determine resistance of gown to the penetration of water by impact	Level 3: ≤ 1.0 gm	Pass
AATCC 127:2018 Standard Test Method for Water Resistance: Hydrostatic Pressure	Determine resistance of gown to the penetration of water under hydrostatic pressure	Level 3: ≥ 50 cm	Pass
ASTM - D5034:2017 Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test)	Determine the breaking strength of gown	More or equals to 7 lbs	Pass
ASTM - D5587:2019 Standard Test Method for Tearing Strength of Fabrics by Trapezoid Procedure	Determine the tearing strength of gown	More or equals to 2.3 lbs	Pass
ASTM - D751:2019 Standard Test Methods for Coated Fabrics	Determine if any failure occurs in gown seams	More or equals to 7 lbs	Pass
ASTM – D3776:2020 Standard Test Methods for Mass Per Unit Area (Weight) of Fabric	Determine the fabric weight	N/A	N/A

Flammability Test Method Standard for Flammability of Clothing Textiles (16 CFR Part 1610)	To test the clothing textile flammability	Class I Normal Flammability Result	Pass
ISO 9073-10 Textiles - Test Method for Nonwovens Part 10: Lint & other Particles Generation in the Dry State	Characterize the size and quantity of the lint generation	N/A	N/A

Table 3: Biocompatibility Tests

Test Method	Purpose	Acceptance Criteria	Results
In vitro Cytotoxicity ISO 10993-5:2009	To determine if device extract is cytotoxic	The device must be non-cytotoxic	Under the study conditions non-cytotoxic
Primary Skin Irritation ISO 10993-10:2010	To determine if device is a skin irritant	The device must be a non-irritant	Under the study conditions not an irritant
Dermal Sensitization ISO 10993-10:2010	To determine if device is a dermal sensitizer	The device must be a non-sensitizer	Under the study conditions not a sensitizer

10. Conclusions:

Based on the non-clinical tests performed, the subject device is as safe, as effective, and performs as well as the legally marketed predicate device, K160337.