January 23, 2022

Danameco Medical Joint Stock Corporation
Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K213970
Trade/Device Name: D-Care Surgical Face Mask 3 Ply, D-Care Medical Face Mask 3 Ply
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical apparel
Regulatory Class: Class II
Product Code: FXX
Dated: December 18, 2021
Received: December 20, 2021

Dear Prithul Bom:

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, 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213970

Device Name
D-Care Surgical Face Mask 3 Ply, D-Care Medical Face Mask 3 Ply

Indications for Use *(Describe)*
The D-Care Surgical Face Mask 3 Ply, D-Care Medical Face Mask 3 Ply are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. The surgical face masks are intended for use in infection control practices to reduce the potential exposure to blood and body fluids. These are single use, disposable devices, 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
K213970

This 510(k) Summary as per 21 CFR 807.92

Date of submission: January 21, 2022

(1) Applicant information

510(k) Owner/ Applicant:	DANAMECO MEDICAL JOINT STOCK CORPORATION
Address:	**Head office**: DANAMECO MEDICAL JOINT STOCK CORPORATION No 12, Trinh Cong Son Street, Hoa Cuong Nam, Hai Chau District, 550000, Da Nang City, Viet Nam **Factory**: Quang Nam Medical Device Factory- Brand of Danameco Medical Joint Stock Corporation Trang Nhat 2 Industrial Zone, Dien Hoa Commune, Dien Ban Town, 560000 Quang Nam Province, Viet Nam.
Contact:	Huynh Thi Li Li (Ms.)
Email:	info@danameco.com; qa@danameco.com
Phone:	(+84)-236-3849833
Owner/Operator Number:	10071934
FEI Number:	3016970619
US Agent:	Emergo Global Representation LLC at address: 2500 Bee Cave Road, Building 1, Suite 300, Austin, TX US 78746
Contact of US agent:	Michael van der Woude, Phone: 512 3279997, Email: USAgent@UL.com
Correspondent:	Regulatory Technology Services at address: 1000 Westgate Drive, Suite #510, Saint Paul, Minnesota, 55114

Contact of Correspondent: Ms. Prithul Bom - Accredited Person, Reviewer

Phone 612-963-0379
Email: prithul.bom@rts3pro.com

(2) Subject device

Trade name:	D-Care Surgical Face Mask 3 Ply, D-Care Medical Face Mask 3 Ply
Model number:	KTY3PLYKV/KTY3PLYVT
Common Name:	Surgical Face Mask
Classification Name:	Masks, Surgical
Review Panel:	General Hospital
Regulation Medical Specialty:	General & Plastic Surgery
Product Code:	FXX
Device Classification:	Class II per 21 CFR §878.4040

(3) Predicate device

Submitter:	Zhejiang Hongyu Medicali Commodity Co.,Ltd
Device name:	Surgical Face Mask
510(k) number:	K211897
Product Code:	FXX
Device Classification:	Class II per 21 CFR §878.4040

(4) Description of device

The subject device is three-layers, flat-pleated masks constructed of nonwoven polypropylene materials, the inner and outer layers are made of polypropylene non-woven, and the middle layer is made of melt blown polypropylene.

The subject device is provided with ear loops. Ear loops is made of 80% polyester 20% spandex, not made with natural rubber latex.

A polypropylene wire nose piece is placed within the binding for comfort and individualized fit, allow the user to fit the facemask around their nose.

The subject device is provided in blue color. The blue colorant is made of polypropylene master batch.

This subject device is provided with size 17.5 cm ± 0.5 cm.

The subject device is single-use, disposable devices, provided non-sterile.

(5) Indications for use

The D-Care Surgical Face Mask 3 Ply, D-Care Medical Face Mask 3 Ply are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. The surgical face masks are intended for use in infection control practices to reduce the potential exposure to blood and body fluids. These are single use, disposable devices, provided non-sterile.

(6) Comparison of Technological Characteristics and Performance testing with the Predicate device

Item	Subject Device	Predicate Device	Comparison
510 (k) number	-	K211897	Not applicable
Applicant	DANAMECO MEDICAL JOINT STOCK CORPORATION	ZHEJIANG HONGYU MEDICALI COMMODITY CO., LTD	Not applicable
Product Name	D-Care Surgical Face Mask 3 Ply, D-Care Medical Face Mask 3 Ply	Surgical Face mask	Not applicable
Model number	KTY3PLYKV/KTY3PLYVT	Ear loops	Not applicable
Device class	Class II Device, FXX (21 CFR 878.4040)	Class II Device, FXX (21 CFR 878.4040)	Same

Indications for Use	The D-Care Surgical Face Mask 3 Ply, D-Care Medical Face Mask 3 Ply are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. The surgical face masks are intended for use in infection control practices to reduce the potential exposure to blood and body fluids. These are single use, disposable devices, provided non-sterile.	The Surgical Face Mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. This face mask is intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This is single use, disposable device, provided non-sterile.	Same
Material			
Outer layer	Polypropylene non-woven	Spunbond polypropylene	Same
Middle layer	Polypropylene meltblown	Meltblown polypropylene	Same
Inner layer	Polypropylene non-woven	Spunbond polypropylene	Same
Nose piece	Polypropylene	Iron core coated with polypropylene resin	Different
Design Features	Ear loops: 80% polyester 20% spandex	Ear loops: polyester + spandex	Similar
Mask Style	Flat Pleated	Flat Pleated	Same
Color	Blue	Blue	Same
Specification and Dimension	Length: 17.5cm±0.5cm Width: 9.5cm±0.5cm	Length: 17.5cm±0.2cm Width: 9.5cm±0.2cm	Similar
Dimension ear loops	17cm±0.5cm	17cm±0.2cm	Similar
OTC use	Yes	Yes	Same
Sterility	Non-Sterile	Non-Sterile	Same
Use	Single Use, Disposable	Single Use, Disposable	Same
Performance Characteristics			
Fluid Resistance Performance ASTM F1862	Pass at 160 mmHg (Level 3 Fluid Resistance)	Pass at 160 mmHg (Level 3 Fluid Resistance)	Same

Particulate Filtration Efficiency ASTM F2299	≥99% at 0.1μm	≥99% at 0.1μm	Same
Bacterial Filtration Efficiency ASTM F2101-19	≥99%	≥99%	Same
Differential Pressure (Delta P)	< 4 mmH_2O/cm^2	< 4 mmH_2O/cm^2	Same
Flammability 16 CFR 1610	Class 1	Class 1	Same
Biocompatibility			
Cytotoxicity ISO 10993-5	Under the conditions of the studies, the subject device is non-cytotoxic	Under the conditions of the study, the device extract was determined to be non-cytotoxic	Same
Irritation ISO 10993-10	Under the conditions of the studies, the subject device is non-irritating	Under the conditions of the study, the device extract was determined to be non-irritant	Same
Sensitization ISO 10993-10	Under the conditions of the studies, the subject device is non-sensitizing	Under the conditions of the study, the device extract was determined to be non-sensitizer	Same

The subject device is same indication for use, design feature, design style, component of material (except nose piece), performance characteristics and biocompatibility with predicate device, similar dimension of size in comparison with predicate device.
The component of ear loop of subject device is similar with predicate device but clearly claim the percent of composition.
The subject device is different material of nose piece to predicate device. The subject device which was included the nose piece had been tested and the result was complied with acceptance criteria.

(7) Summary of Non-clinical test

Performance characteristics			
Test Method	**Subject Device**	**Acceptance Criteria**	**Conclusion**
Fluid Resistance Performance ASTM F1862	≥29 out of 32 passed in 160 mmHg (Level 3)	29 out of 32 passed in 160 mmHg (Level 3)	Pass
Particulate Filtration Efficiency ASTM F2299	≥99% at 0.1μm	≥98% at 0.1μm	Pass
Bacterial Filtration Efficiency ASTM F2101-19	≥99%	≥98%	Pass
Differential Pressure (Delta P)	< 4 mmH_2O/cm^2	< 6.0 mm H_2O/cm^2	Pass
Flammability 16 CFR 1610	Class 1(≥ 3.5 seconds)	Class 1 (≥ 3.5 seconds)	Pass

Performance testing were performed on three non-consecutive lots to support that the performance specification are maintained cross production lots and the lot-to-lot variability in performance is acceptable.

Sample size of each lot is complied with ISO 2859-1, general inspection level II as FDA recommendation and acceptance quality limit (AQL) of 4%.

The results of performance testing of subject device demonstrate that the subject device met all design specification as was same to predicate device, complied with requirements in guidance: “Surgical Masks – Premarket Notification [510(k)] Submissions”, complied with standard ASTM F2100 at level 3.

Biocompatibility			
Standard	**Subject Device**	**Acceptance Criteria**	**Conclusion**
Cytotoxicity **ISO 10993-5**	Under the conditions of the studies, the device is non-cytotoxic.	The device is non-cytotoxic	Pass

Skin Sensitization test **ISO 10993-10**	Under the conditions of the studies, the subject device is non-sensitizing	The device is non-sensitizing	Pass
Skin Irritation test **ISO 10993-10**	Under the conditions of the studies, the device is non-irritating.	The device is non-irritating	Pass

The biocompatibility evaluation of this subject device was conducted according to ISO 10993-1: nature of body contact of the subject device is belonged to category Surface device, intact skin, with contact duration A-limited (≤24h)

The subject device was evaluated in its final finished form, in blue color.

The results of biocompatibility testing of subject device demonstrate that the subject device is biocompatible and safe for its intended use.

(8) Summary of Clinical test

No clinical study is included in this submission.

(9) Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the proposed subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate device.