July 24, 2020

DemeTECH Corporation
Tracy Chadwrick
Quality Director
14175 NW 60th Avenue
Miami Lakes, Florida 33014

Re: K201479
Trade/Device Name: DemeMASK
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: July 16, 2020
Received: July 21, 2020

Dear Tracy Chadwrick:

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,

Elizabeth F. Claverie, MS
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)*
K201479

Device Name
DemeMASK Surgical Mask

Indications for Use *(Describe)*
The Disposable Surgical Face Masks are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. These face masks are intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This is a single use, disposable 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.

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

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510(K) Summary

This summary is submitted in accordance with the Safe Medical Device Act (SMDA) of 1990 and Title 21 CFR § 807.92.

A. Applicant:

DemeTECH Corporation
14175 NW 60th Avenue
Miami Lakes, FL. 33014

B. Contact Person:

Tracy Chadwrick
Phone: 305-824-1048
Tracy.Chadwrick@demetech.us

C. Date Summary Prepared: July 23, 2020

D. Device

Trade Name:	DemeMASK Surgical Mask
Common Name:	Surgical Face Mask

Regulatory Information

Classification Name:	Surgical Face Mask
Classification:	Class II
Product code:	FXX
Regulation Number:	878.4040
Review Panel:	Surgical Apparel

E. Predicate Device:

510(k)	K173062
Trade Name:	Non Woven Face Mask (Model: VQN0185W (earloop)
Manufacturer:	V&Q Manufacturing Corporation
Address:	#B1614 Optical Valley Time Square Wuhan, Hubei, CHINA

F. Device Description:

The proposed devices are 3-ply, flat-pleated surgical masks. The devices are manufactured with three layers, the inner and outer layers are made of spunbond polypropylene, and the middle layer is made of melt blown polypropylene filter. There surgical masks to be secured on users via earloops made of spandex and nylon. The devices are sold non-sterile and are intended to be single use and disposable.

Contact
Type: Surface Device - Intact Skin
Contact Duration: Limited - Less than 24 hours

G. Indications for Use:

The Disposable Surgical Face Masks are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. These face masks are intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This is a single use, disposable device provided non-sterile.

H. Technological Characteristic Comparison

Device	**DemeMASK**	**Predicate Device**	**Comparison**
510 (k)	K201479	K173062	N/A
Manufacturer	DemeTECH Corporation	V&Q Manufacturing Corporation	N/A
Product Name	Surgical Face Mask	Surgical Face Mask	Same
Classification	Class II Device, FXX (21 CFR 878.4040)	Class II Device, FXX (21 CFR 878.4040)	Same
Indications for Use	The Disposable Surgical Face Masks are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. These face masks are intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This is a single use, disposable device provided non-sterile.	The Surgical Face Masks are intended for single use by operating room personnel and other general healthcare workers to protect both patients and healthcare workers against transfer of microorganisms, blood and body fluids, and particulate materials.	Similar
Material			
Outer facing layer	Spunbond polypropylene	Spunbond polypropylene	Same
Middle layer	Meltblown polypropylene filter	Meltblown polypropylene filter	Same
Inner facing layer	Spunbond polypropylene	Spunbond polypropylene	Same
Nose piece	Galvanized wire coated with polyethylene	White aluminum strip with Polypropylene covering	Similar
Ear loops/Ties	Spandex and Nylon – Not made from natural rubber latex	Urethane Elastic – Not made from natural rubber latex	Similar
Mask Style	Flat Pleated	Flat Pleated	Same

Specification and Dimension	Length: 17.5 cm±1 cm Width: 9.5 cm±1 cm	175mm X 95 mm	Same
OTC use	Yes	Yes	Same
Sterility	Non-Sterile	Non-Sterile	Same
Use	Single Use, Disposable	Single Use, Disposable	Same

Device	DemeMASK	Predicate Device	Comparison
Fluid Resistance Performance **ASTM F1862**	Pass at 160 mmHg (Level 3 Fluid Resistance)	Pass at 120 mmHg (Level 2 Fluid Resistance)	Different
Particulate Filtration Efficiency **ASTM F2299**	Pass at ≥99%	Pass at 99.74%	Similar
Bacterial Filtration Efficiency **ASTMF2101**	Pass at ≥99%	Pass at 99.4%	Similar
Differential Pressure (Delta P) **MIL-M-36954C**	Average 3.6 mmH_2O/cm^2	Average 2.7 mmH_2O/cm^2	Similar
Flammability **16 CFR 1610**	Class 1	Class 1	Same
Biocompatibility **ISO 10993-5 and ISO 10993-10**	Under the conditions of the studies employed, the device is non-cytotoxic, non-sensitizing, and non-irritating.	Under the conditions of the studies employed, the device is non-cytotoxic, non-sensitizing, and non-irritating.	Same

I. Table of Conformity to Standards

Standards	Name
ASTM F1862/F1862M-17	Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity)
ASTM F2100-19	Standard Specification for Performance of Materials Used in Medical Face Masks
ASTM F2101-19	Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials Using a Biological Aerosol of Staphylococcus aureus
ISO 10993-5	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
ISO 10993-10	Biological evaluation of medical devices - Part 10: Tests for Irritation and skin sensitization
MIL-M-36954C	Differential Pressure (Delta-P)

ASTM F2299/F2299M-03	Standard Test Method for Determining the Initial Efficiency of Materials Used in Medical Face Masks to Penetration by Particulates Using Latex Spheres

J. Table of Performance Testing-Bench

Standards	DemeMask	Acceptance Criteria	Result
Resistance to penetration by synthetic blood ASTM F1862	32 out of 32 passed in 160 mm Hg	29 out of 32 passed in 160 mm Hg	Pass
Sub-micron particulate filtration efficiency at 0.1 micron ASTM F2299	≥99%	≥98%	Pass
Bacterial filtration efficiency ASTM F2101-19	≥99%	≥98%	Pass
Differential pressure MIL-M-36954	Average 3.6 mmH_2O/cm^2	< 6.0	Pass
Flame spread 16 CFR 1610	Class 1 Non-Flammable	Class 1 Non-Flammable	Pass

K. Table of Biocompatibility Testing

Standards	Proposed Device	Result
Cytotoxicity ISO 10993-5	Under the conditions of the study, the device is non-cytotoxic.	Pass
Skin Sensitization Test ISO 10993-10	Under the conditions of the study, the device is non-sensitizing.	Pass
Skin Irritation Test ISO 10993-10	Under the conditions of the study, the device is non-irritating.	Pass

L. Clinical Tests Performed

No clinical study is included in this submission.

M. Conclusion

The conclusions drawn from the nonclinical and clinical tests demonstrate that the subject device is as safe, as effective, and performs as well as or better than the legally marketed device K173062, Nonwoven Surgical Mask manufactured by V&Q Manufacturing Corporation.