November 14, 2022

America's Supply Chains
% Prithul Bom, MBA, MS, RAC (US, EU), CSQE
Accredited Person, Reviewer
Regulatory Technology Services, LLC
1000 Westgate Drive, Suite #510k
Saint Paul, Minnesota 55114

Re: K222749
Trade/Device Name: High Fluid-Resistant Surgical and Procedure Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: October 31, 2022
Received: November 1, 2022

Dear Ms. 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,

Brent Showalter -S

Brent Showalter, Ph.D.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic 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)*
K222749

Device Name
High Fluid-Resistant Surgical and Procedure Mask

Indications for Use *(Describe)*

The High Fluid-Resistant Surgical and Procedure Mask is 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 potential exposure to blood and body fluids. The face mask 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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AMERICA'S SUPPLY CHAINS

510(k) Summary

This summary of 510(k) is submitted in accordance with the requirements of 21 CFR §807.92:

I. SUBMITTER

America's Supply Chains
7555 Warren Pkwy, Unit 486
Frisco, TX 75034 USA

Contact Person: Paul Park
Tel: (617) 800-3602
Email: americasupplychains@gmail.com
Date Prepared: September 06, 2022

II. DEVICE

Name of Device:	High Fluid-Resistant Surgical and Procedure Mask
Common or Usual Name:	Surgical Mask
Classification Name:	Surgical Apparel
Regulatory Class:	Class II (21 CFR §878.4040)
Regulation Medical Specialty:	General & Plastic Surgery
510k Review Panel:	General Hospital
Product Code:	FXX

III. PREDICATE DEVICE

Predicate Manufacturer:	3M Health Care
Predicate Trade Name:	3M™ High Fluid- Resistant Procedure Mask Model Number 1840
Predicate 510(k):	K191355

IV. DEVICE DESCRIPTION

The High Fluid-Resistant Surgical and Procedure Mask is composed of four-layers and is flat-pleated. The mask materials consist of an outer cover web (polypropylene spunbond, white), insertion layer (polypropylene, spunbond, white), filter web (polypropylene melt-blown, white) and inner cover web (polypropylene thermal-bonded, white). Each mask contains ear loops to secure the mask to the user's face and mouth, as well as a fully enclosed, soft, bendable nose piece to fit over the nose.

This device is not made from natural rubber latex.

V. INDICATIONS FOR USE

The High Fluid-Resistant Surgical and Procedure Mask is 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 potential exposure to blood and body fluids. The face mask is a single use, disposable device, provided non-sterile.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The following characteristics were compared between the subject device and the predicate device in Table 1 below.

[Table 1: Comparison of Predicate Devices]

Description	Subject Device High Fluid-Resistant Surgical and Procedure Mask ASTM Level 3	Predicate Device (K191355) 1840 3M™ High Fluid-Resistant Procedure Mask ASTM Level 3	Comparison
Intended Use/ Indications for Use	The High fluid-Resistant Surgical and Procedure 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 potential exposure to blood and body fluids. This is a single use, disposable device, provided non-sterile.	3M™ High Fluid- Resistant Procedure Mask is 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 potential exposure to blood and body fluids. This is a single use, disposable device, provided non-sterile.	Same
Materials			
Outer Cover Web	Polypropylene Spunbond, white	Polypropylene Spunbond, green	Similar (Subject device does not have colorant)
Insertion	Polypropylene Spunbond, white	Polypropylene Spunbond, white	Same
Filter Web (Middle)	Polypropylene Meltblown, white	Polypropylene Meltblown, white	Same
Inner Cover Web	Polypropylene Thermalbonded, white	Polypropylene Thermalbonded, white	Same
Nose Piece	Polyethylene Coated Steel Wire	Polyethylene Coated Steel Wire	Same
Ear Loops	Spandex elastic cord	Spandex elastic cord	Same

Style	Flat - Pleated	Flat - Pleated	Same
Multiple Layers	4-Ply	4-Ply	Same
Colors	White (Outer)	Green (Outer)	Different (Subject device does not have colorant)
Dimension (Width)	3.5” ± 0.3”	3.5” ± 0.3”	Same
Dimension (Length)	6.9” ± 0.2”	6.9” ± 0.2”	Same
OTC Use	Yes	Yes	Same
Sterility	Non-Sterile	Non-Sterile	Same
Use	Single Use	Single Use	Same
ASTM F2100 Level	Level 3	Level 3	Same

VII. PERFORMANCE DATA

The subject device was tested and conformed to the following standards and the requirements stated in the Guidance for Industry and FDA Staff: Surgical Masks – Premarket Notification [510(k)] Submission issued on March 5, 2004. A summary of the benchtop performance testing results is provided below in Table 2.

[Table 2: Benchtop Performance Testing]

Item	Proposed Device High Fluid-Resistant Surgical and Procedure Mask ASTM Level 3	ASTM Level 3 Mask Standard Acceptance Criteria	Predicate Device (K191355) 3M™ High Fluid-Resistant Procedure Mask ASTM Level 3	Result
ASTM F1862/ISO 22609 Fluid Resistance	Three non-sequential lots of 32 (total of 96, AQL 4.0) passed at 160mmHg Lot 1: 32 /32 pass Lot 2: 32 /32 pass Lot 3: 32 /32 pass	AQL 4%, single sampling plan, 29 out of 32 Pass at 160mmHg	32/32 Passed at 160mm Hg	Pass
ASTM F2299 Particulate Filtration Efficiency	Three non-sequential lots of 32 (total of 96, AQL 4.0) passed at ≥98% Lot 1: 32/32 pass Lot 2: 32/32 pass Lot 3: 32/32 pass	≥ 98%	32/32 Passed at ≥98% @ 0.1 micron	Pass
Bacterial Filtration Efficiency ASTM F2101	Three non-sequential lots of 32 (total of 96, AQL 4.0) passed at ≥98% Lot 1: 32/32 pass Lot 2: 32/32 pass Lot 3: 32/32 pass	≥ 98%	31/32 Passed at ≥98%	Pass
Differential Pressure ASTM	Three non-sequential lots of 32 (total of 96) passed at <6mmH2O/cm2	AQL 4%, single sampling plan,	32/32 Passed at <5mmH2O/cm2 MIL-M36954C	Pass

F2100/EN 14683:2019	MIL-M36954C Lot 1: 32/32 pass Lot 2: 32/32 pass Lot 3: 31/32 pass	<6.0 mmH2O/cm2		
Class 1 Flammability 16 CFR 1610	Three non-sequential lots of 32 (total of 96, AQL 4.0) passed Class 1 16 CFR 1610 Lot 1: Class 1, IBE Lot 2: Class 1, IBE Lot 3: Class 1, IBE	Class 1 < 3.5 second burn time	5/5 Passed ≥3 Seconds burn time	Pass

Sterilization & Shelf-life Testing

Not Applicable (This is a non-sterile device and shelf-life is not applicable to this device because of low likelihood of time-dependent product degradation.)

Biocompatibility Testing

Biocompatibility testing was performed in accordance with ISO 10993-1:2018. Specifically, the following testing endpoints were evaluated.

[Table 3: Biocompatibility Testing]

Biocompatibility Testing Endpoints	Acceptance Criteria	Result
Cytotoxicity – ISO 10993-5 Skin Sensitization – ISO 10993-10 Skin Irritation – ISO 10993-10	Non-Cytotoxic Non- Sensitizing Non-Irritating	Pass Pass Pass

[Table 4: Summary of Non-Clinical Performance Testing]

The following standards have been used to evaluate the High Fluid-Resistant Surgical and Procedure Mask:

ASTM F2101-19/EN 14683:2019	Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus
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 F2299-17	Standard Test Method for Determining the Initial Efficiency of Materials Used in Medical Face Masks to Penetration by Particulates Using Latex Spheres
ASTM F2100/EN 14683:2019 ANNEX C	Standard Test Method for Differential Pressure Standard Specification for Performance of Materials Used in Medical Face Masks
16 CFR Part 1610 EN 14683:2019 ANNEX C	Standard for Flammability
ISO 10993-5	ISO 10993-5 Third edition 2009-06-01 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
ISO 10993-10	ISO 10993-10 Third Edition 2010-08-01 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

Software Verification and Validation Testing

Not Applicable (Passive Device)

Electrical safety and electromagnetic compatibility (EMC)

Not Applicable (Passive Device)

Animal Study

Animal performance testing was not required to demonstrate safety and effectiveness of the device.

Human Clinical Performance Testing

Clinical testing was not required to demonstrate the safety and effectiveness of the device.

VIII. CONCLUSIONS

The conclusions drawn from the performance data demonstrate that the subject device is as safe, effective, and performs as well as or better than the legally marketed device K191355, 3M™ High Fluid- Resistant Procedure Mask manufactured by 3M Health Care.