September 11, 2019

3M Health Care
Angie Draper
Sr. Regulatory Affairs Associate
3M Center, 2510 Conway Ave., Building 275-5W-06
St. Paul, Minnesota 55144

Re: K191355
Trade/Device Name: 3M™ High Fluid-Resistant Surgical Mask and 3M™ High Fluid-Resistant Procedure Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: August 19, 2019
Received: August 20, 2019

Dear Angie Draper:

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 Elizabeth Claverie, M.S.
Assistant Director for THT4B2
Acting Assistant Director for THT4B1
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)*

K191355

Device Name
3M™ High Fluid-Resistant Surgical Mask
3M™ High Fluid-Resistant Procedure Mask

Indications for Use *(Describe)*

The 3M™ High Fluid-Resistant Surgical Mask and 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. The face mask is single use, disposable device, provided non-sterile.

1835	3M™ High Fluid-Resistant Surgical Mask
1835FS	3M™ High Fluid-Resistant Surgical Mask with Face Shield
1840	3M™ High Fluid-Resistant Procedure Mask
1840FS	3M™ High Fluid-Resistant Procedure Mask with Face Shield

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

K191355

3M™ High Fluid-Resistant Surgical Mask
3M™ High Fluid-Resistant Procedure Mask

Sponsor Information:	3M Health Care 2510 Conway Ave 3M Center, Building 275-5W-06 St. Paul, MN 55144
Contact Person:	Angie Draper Title: Sr. Regulatory Affairs Associate Phone Number: (651) 733-1179 Fax Number: (651) 737-5320 email: amdraper01@mmm.com
Date of Summary:	April 30, 2019
Common Name:	Surgical Mask
Classification Name:	Surgical Apparel
Proprietary Name:	3M™ High Fluid-Resistant Surgical Mask 3M™ High Fluid-Resistant Procedure Mask
Review Panel:	General and Plastic Surgery
Product Code:	FXX
Device Classification:	Class II per (21 CFR §878.4040)
Predicate Device:	Kimberly-Clark* KC300 Surgical Mask (K131879)
Intended Use:	The 3M™ High Fluid-Resistant Surgical Mask and 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. The face mask is single use, disposable device, provided non-sterile.

Available Model Numbers

1835	3M™ High Fluid-Resistant Surgical Mask
1835FS	3M™ High Fluid-Resistant Surgical Mask with Face Shield
1840	3M™ High Fluid-Resistant Procedure Mask
1845FS	3M™ High Fluid-Resistant Procedure Mask with Face Shield

Device Description:

The 3M™ High Fluid-Resistant Surgical Mask and 3M™ High Fluid-Resistant Procedure Mask are composed of four-layers and are flat-pleated. The mask materials consist of an outer cover web (polypropylene spunbond, green), insertion layer (polypropylene, spunbond, white), filter web (polypropylene melt-blown, white) and inner cover web (polypropylene thermal-bonded, white). Each mask contains tie strings or ear loops to secure the mask over the users' mouth and face and includes a malleable nosepiece to provide a firm fit over the nose. The mask may also contain a face shield (FS) made from a polyethylene terephthalate film, which includes an anti-reflection strip. The face shield is adhered to the top edge of the mask to cover the upper part of the face. The mask is a single use, disposable device, provided non-sterile.

This device is not made from Natural Rubber Latex.

Technological Characteristics:

The 3M™ High Fluid-Resistant Surgical Mask and 3M™ High Fluid-Resistant Procedure Mask are compared with the predicate device (KC300 Surgical Mask (K131879)). The results are shown below in the Technological Characteristics Comparison Table:

Item(S)	**Subject Device (K191355)** 3M™ High Fluid-Resistant Surgical Mask ASTM Level 3	**Subject Device (K191355)** 3M™ High Fluid-Resistant Procedure Mask K191355 ASTM Level 3	**Predicate Device(K131879)** KC300 Face Mask ASTM Level 3	**Comparison**
Intended Use/ Indications for Use	3M™ High Fluid- Resistant Surgical 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.	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.	The Kimberly-Clark KC300 Surgical 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 the potential exposure to blood and body fluids. This is a single use, disposable device, provided non- sterile.	Same
Materials				
Outer Cover Web	Polypropylene Spunbond, green	Polypropylene Spunbond, green	Polyethylene/Polyester with pink and blue ink print	Different
Insertion	Polypropylene Spunbond, white	Polypropylene Spunbond, white	Unknown	Not known
Filter Web (Middle)	Polypropylene Meltblown, white	Polypropylene Meltblown, white	Polypropylene Spunbond and Polypropylene Melt-blown	Different
Inner Cover Web	Polypropylene Thermal-bonded, white	Polypropylene Thermal-bonded, white	Polyethylene/Polyester	Different
Nose Wire	Polyethylene Coated Steel Wire	Polyethylene Coated Steel Wire	Unknown	Not known
Edge wrap	Polypropylene Spunbond, white or Polyethylene Terephthalate, white	Polypropylene Spunbond, white or Polyethylene Terephthalate, white	Polyester Spunlace or Polypropylene Spunbond	Different
Ear Loops	Not Applicable	Spandex elastic cord (polyurethane core with polyethylene terephthalate /nylon cover)	Polyester/Lycra Knitted	Different
Tie Strings	Polypropylene Spunbond, White or Polyethylene Terephthalate, white	Not Applicable	Polypropylene Spunbond	Different
Design Features				
Colors	Green (Outer)	Green (Outer)	Multiple (Outer)	Different
Style	Flat - Pleated	Flat - Pleated	Flat - Pleated	Same

Multiple Layers	Yes	Yes	Yes	Same
Single Use	Yes	Yes	Yes	Same
Sterility				
Sterile	Non-Sterile	Non-Sterile	Non-Sterile	Same
Dimensions				
Length	6.9" ± 0.2"	6.9" ± 0.2"	6 5" ± 0.75"	Different
Width	3.5" ± 0.3"	3.5" ± 0.3"	4" ± 0.75"	Different
Technological Characteristics Product Barrier Specifications Per ASTM F2100 – Meets Level 3				
Particulate Filtration Efficiency (PFE)	32/32 Passed at ≥98% @ 0.1 micron ASTM F2299	32/32 Passed at ≥98% @ 0.1 micron ASTM F2299	Pass at ≥98% @ 0.1 micron ASTM F2299	Same
Fluid Resistance	32/32 Passed at 160mm Hg ASTM F1862	32/32 Passed at 160mm Hg ASTM F1862	Fluid Resistant 160mm Hg ASTM F1862	Same
Bacterial Filtration Efficiency (BFE)	31/32 Passed at ≥98% ASTM F2101	31/32 Passed at ≥98% ASTM F2101	Pass at ≥98% ASTM F2101	Same
Differential Pressure	32/32 Passed at <5 mmH_2O/cm^2 MIL-M36954C	32/32 Passed at <5 mmH_2O/cm^2 MIL-M36954C	Pass at <5 mmH_2O/cm^2 MIL-M36954C	Same
Flammability	5/5 Passed ≥3 Seconds burn time - Class 1 CFR 16 1610	5/5 Passed ≥3 Seconds burn time - Class 1 CFR 16 1610	Class 1 CFR 16 1610	Same
Biocompatibility				
Results	Non-cytotoxic, Non-sensitizing, Non-irritating	Non-cytotoxic, Non-sensitizing, Non-irritating	Non-cytotoxic, Non-sensitizing, Non- irritating	Same

The following standards have been met for the 3M™ High Fluid-Resistant Surgical Mask and 3M™ High Fluid-Resistant Procedure Mask

ASTM F2100	Standard Specification for Performance of Materials Used in Medical Face Masks
ASTM F1862	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	Standard Test Method for Determining the Initial Efficiency of Materials Used in Medical Face Masks to Penetration by Particulates Using Latex Spheres
ASTM F2101	Standard Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of *Staphylococcus aureus*
MIL-M- 36954C	Military Specification, Mask, Surgical, Disposable
16 CFR Part 1610	Standard for the Flammability of Clothing
ISO10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
ISO10993-5	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity of medical devices
ISO10993-10	Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization

Conclusion:

The conclusion drawn from the nonclinical tests demonstrates that the subject devices in 510(K) submission K191355, the 3M™ High Fluid-Resistant Surgical Mask and 3M™ High Fluid-Resistant Procedure Mask are as safe, as effective, and performs as well as or better than the legally marketed predicate device K131879.