March 11, 2019

3M Health Care
Kristin Totushek
Advanced Regulatory Affairs Specialist
3M Health Care
2510 Conway Ave, Building 275-5W-06
St. Paul, MN 55144

Re: K180874
Trade/Device Name: 3M High Performance Surgical Mask, 3M High Performance Surgical Mask with Face Shield
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical apparel
Regulatory Class: Class II
Product Code: FXX
Dated: June 14, 2018
Received: June 20, 2018

Dear Kristin Totushek:

This letter corrects our substantially equivalent letter of July 31, 2018.

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Clarence W. Murray Iii III -S

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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)*
K180874

Device Name

3M™ High Performance Surgical Mask

Indications for Use *(Describe)*

The 3M™ High Performance Surgical Mask is intended to be worn to protect both patient and healthcare personnel from transfer of microorganisms, body fluids, and particulate material. These face mask(s) are intended for use in infection control practices to reduce potential exposure to blood and body fluids. This is a single use, disposable device(s) and provided non-sterile.

3M™ High Performance Surgical Mask - 1838R
3M™ High Performance Surgical Mask with Face Shield - 1838FSG

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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Sponsor Information:	3M Health Care 2510 Conway Ave 3M Center, Building 275-5W-06 St. Paul, MN 55144
Contact Person:	Kristin Totushek, RAC Title: Advanced Regulatory Affairs Specialist (651) 736-6117 ktotushek@mmm.com
Date of Summary:	July 30, 2018
Proprietary Name:	3M™ High Performance Surgical Mask
Common Name:	Surgical Mask
Classification Name:	Surgical Apparel
Review Panel:	General and Plastic Surgery
Product Code:	FXX
Device Classification:	Class II per (21 CFR §878.4040)
Predicate Device:	Fluidshield* Surgical Mask with Expanded Chamber (K143287)
Intended Use:	The 3M™ High Performance Surgical Mask is intended to be worn to protect both patient and healthcare personnel from transfer of microorganisms, body fluids, and particulate material. These face mask(s) are intended for use in infection control practices to reduce potential exposure to blood and body fluids. This is a single use, disposable device(s) and provided non-sterile.

Model Numbers:
1838R 3M™ High Performance Surgical Mask
1838FSG 3M™ High Performance Surgical Mask with Face Shield

Device Description:
The 3M™ High Performance Surgical Mask has a duckbill design consisting of three layers that are comprised of an (polypropylene spunbond) inner and outer cover web and (polypropylene melt blown) filter web. The mask has ties to secure the mask over the users' mouth and face and includes a malleable nosepiece to provide a firm fit over the nose. They may be produced with or without a face shield. This is a single use, disposable device, provided non-sterile.

This device is not made with Natural Rubber Latex.

Technological Characteristics:
The 3M™ High Performance Surgical Mask is substantially equivalent to the current Fluidshield* Surgical Mask with Expanded Chamber (K143287) as these products conform with ASTM F2100 standard and meet Level 2 performance specifications. Both the submission and predicate products address, "Guidance for Industry and FDA Staff: Surgical Masks –Premarket Notification 510(K) submissions. Issued March 5, 2004".

Comparison to Predicate Device:
The 3M™ High Performance Surgical Mask, the subject of this submission, is substantially equivalent to the Fluidshield* Surgical Mask with Expanded Chamber cleared under K143287. The submission and predicate devices claim Level 2 in accordance with ASTM F2100 product standard.

Feature	K180874 3M™ High Performance Surgical Mask 1838R	K180874 3M™ High Performance Surgical Mask with Face Shield 1838FSG	Predicate Device Halyard Heath, Inc. Fluidshield* Surgical Mask with Expanded Chamber K143287
Intended Use	3M™ High Performance Surgical Mask is intended to be worn to protect 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(s), provided non-sterile.	3M™ High Performance Surgical Mask is intended to be worn to protect 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(s), provided non-sterile.	The Expanded Chamber Surgical Face Mask is intended to be worn to protect 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(s), provided non-sterile.
Materials			
Outer Cover Web	Polypropylene Spunbond, (w Print) – Upper Top Half Polypropylene Spunbond, White – Lower Bottom Half	Polypropylene Spunbond, (w Print) – Upper Top Half Polypropylene Spunbond, White – Lower Bottom Half	Polypropylene Spunbond (w Print) – Upper Top Half Polypropylene Spunbond, White – Lower Bottom Half
Middle Web/Filter	Polypropylene Melt Blown	Polypropylene Melt Blown	Polypropylene Spunbond and Polypropylene Melt Blown
Inner Cover Web	Polypropylene Spunbond	Polypropylene Spunbond	Polypropylene/Polyester
Tie Strings	Polypropylene Spunbond or PolyethyleneTerephthalate	Polypropylene Spunbond or PolyethyleneTerephthalate	Polyester Spunbond or Polypropylene Spunbond
Top and Bottom Binding	Polypropylene Spunbond	Polypropylene Spunbond	Polypropylene Spunbond
Nose Piece	Polyethylene coated steel wire	Polyethylene coated steel wire	Wire (Material Unknown)

Feature	**K180874** **3M™ High Performance Surgical Mask** **1838R**	**K180874** **3M™ High Performance Surgical Mask with Face Shield** **1838FSG**	**Predicate Device** **Halyard Heath, Inc. Fluidshield* Surgical Mask with Expanded Chamber** **K143287**
Design Features			
Color	Blue - Outer Cover Web (Upper) White - Outer Cover Web (Lower)	Blue - Outer Cover Web (Upper) White - Outer Cover Web (Lower)	Variety
Face Shield	No	Yes	Yes
Mask Design			
Style	Duckbill	Duckbill	Duckbill
Single Use	Yes	Yes	Yes
Sterility			
Sterile	Non-sterile	Non-sterile	Non-sterile
Specifications and Dimensions			
Length	187 mm ± 4 mm	187 mm ± 4 mm	8.3″ ± 0.4″
Width	107 mm ± 6 mm	107 mm ± 6 mm	7.5″ ± 0.11″
Technological Characteristics **Product Performance Specifications Per ASTM F2100 - Meets ASTM Level 2**			
Fluid	ASTM F1862	ASTM F1862	ASTM F1862
Particulate	ASTM F2299	ASTM F2299	ASTM F2299
Bacterial	ASTM F2101	ASTM F2101	ASTM F2101
Differential	MIL-M36954C	MIL-M36954C	MIL-M36954C
Flammability	16 CFR 1610	16 CFR 1610	16 CFR 1610
Biocompatibility			
Results	Biocompatible, Non-cytotoxic, Non- irritating, Non-Sensitizing	Biocompatible, Non-cytotoxic, Non- irritating, Non-Sensitizing	Biocompatible, Non-cytotoxic, Non-irritating, Non-Sensitizing

The following standards have been met for the 3M™ High Performance Surgical 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	MIL-M36954C - Military Specification, Surgical Mask, Disposable - Differential Pressure (Delta P)
16 CFR Part 1610	Standard for the Flammability of Clothing Textiles
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
ISO10993-10	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

Conclusion:

The conclusions drawn from the nonclinical tests demonstrate that the 3M™ High Performance Surgical Mask is as safe, as effective, and performs as well as or better than the legally marketed predicate device K143287.