March 2, 2021

Fssc, LLC
% Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K202214
Trade/Device Name: IFM Surgical Mask Model SM3
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical apparel
Regulatory Class: Class II
Product Code: FXX
Dated: February 3, 2021
Received: February 17, 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 Ryan Ortega, PhD
Acting 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)*
K202214

Device Name
IFM Surgical Mask

Indications for Use *(Describe)*
The IFM Surgical Mask Model SM3 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.

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

K202214

IFM Surgical Mask Model SM3

Sponsor Information:	FSSC, LLC 3300 West Clark St. Rensselaer, IN 47978 Sponsor Contact: Clayton Geyer Operations Engineer Phone Number: 219-863-8316 Email: clayton@ifmasks.com
Contact Person:	Amy Fowler Regulatory Counsel Pathmaker FDA Law, PLLC 528 Hennepin Ave., Suite 503 Minneapolis, MN 55403
Date of Summary:	March 1, 2021
Common Name:	Surgical Mask
Classification Name:	Surgical Apparel
Proprietary Names:	IFM
Review Panel:	General Hospital
Product Code:	FXX
Device Classification:	Class II per 21 CFR §878.4040
Predicate Device:	3M™ High Fluid-Resistant Procedure Mask (K191355) – Model Number 1840
Intended Use:	The IFM Surgical Mask Model SM3 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.
Device Description:	The IFM Surgical Mask Model SM3 is composed of four-layers and is flat-pleated. The mask materials consist of an outer cover web (polypropylene spunbond, white), insertion layer (polypropylene, melt-blown, white), filter web (polypropylene melt-blown, white) and inner cover web (polypropylene melt-spunbond, white). Each mask contains ear loops to secure the

mask over the user's mouth and nose and includes a malleable nosepiece to provide a firm fit over the nose. The mask is a single use, disposable device, provided non-sterile.

This device is not made with natural rubber latex.

Available Model Numbers SM3 IFM Surgical Mask

Comparison of Subject and Predicate Devices:

Item(s)	**Subject Device (K202214)** IFM Surgical Mask Model SM3 ASTM F2100 Level 3	**Predicate Device (K191355)** 1840 3M™ High Fluid-Resistant Procedure Mask ASTM F2100 Level 3	**Comparison**
Intended Use / Indications for Use	The IFM Surgical Mask Model SM3 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.	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. 1840 - 3M™ High Fluid-Resistant Procedure Mask[1]	Same
Type of Use	Over-The-Counter Use (21 CFR 801 Subpart C)	Over-The-Counter Use (21 CFR 801 Subpart C)	Same
Outer layer	Polypropylene Spunbond, white	Polypropylene Spunbond, green	Similar

[1] The predicate device has four cleared model numbers. The subject device is only being compared to model 1840 3M™ High Fluid-Resistant Procedure Mask

Item(s)	**Subject Device (K202214)** IFM Surgical Mask Model SM3 ASTM F2100 Level 3	**Predicate Device (K191355)** 1840 3M™ High Fluid-Resistant Procedure Mask ASTM F2100 Level 3	**Comparison**
Insertion	Polypropylene Spunbond, white	Polypropylene Spunbond, white	Same
Middle layer	Polypropylene Meltblown, white	Polypropylene Meltblown, white	Same
Inner layer	Polypropylene Meltblown, white	Polypropylene Thermal-bonded, white	Similar
Nose Piece	Polyethylene Strip	Polyethylene Coated Steel Wire	Similar
Edge wrap	Polypropylene Spunbond, white	Polypropylene Spunbond, white or Polyethylene Terephthalate, white	Similar
Ear Loops	Spandex Elastic Cord	Spandex elastic cord (polyurethane core with polyethylene terephthalate /nylon cover)	Similar
Colors	White	Green (Outer)	Different. Subject device does not have colorant.
Style	Flat - Pleated	Flat - Pleated	Same
Multiple Layers	Yes	Yes	Same
Single Use	Yes	Yes	Same
Sterile	Non-Sterile	Non-Sterile	Same

Item(s)	**Subject Device (K202214)** IFM Surgical Mask Model SM3 ASTM F2100 Level 3	**Predicate Device (K191355)** 1840 3M™ High Fluid-Resistant Procedure Mask ASTM F2100 Level 3	**Comparison**
Length	6.63" ± 0.2”	6.9” ± 0.2”	Similar
Width	3.5” ± 0.3”	3.5” ± 0.3”	Same
Particulate Filtration Efficiency (PFE)	Three lots passed at ≥98% @ 0.1 micron ASTM F2299	32/32 Passed at ≥98% @ 0.1 micron ASTM F2299	Similar
Fluid Resistance	Three lots passed at 160mm Hg ASTM F1862	32/32 Passed at 160mm Hg ASTM F1862	Same
Bacterial Filtration Efficiency (BFE)	Three lots passed at ≥98% ASTM F2101	31/32 Passed at ≥98% ASTM F2101	Same
Differential Pressure	Three lots passed at <5 Delta-P (mmH_2O/cm^2) EN 14683:2019, Annex C and ASTM F2100-19	32/32 Passed at <5 mmH_2O/cm^2 MIL-M36954C	Similar
Flammability	Three lots Passed. - Class 1 16 CFR 1610	5/5 Passed ≥3 Seconds burn time - Class 1 16 CFR 1610	Similar
Biocompatibility	Under the conditions of the study the device was found non-cytotoxic; Under the conditions of the study the device was found not an irritant; Under the conditions of the study the device was found not a sensitizer;	Under the conditions of the study the device was found non-cytotoxic; Under the conditions of the study the device was found not an irritant; Under the conditions of the study the device was found not a sensitizer;	Same

Performance Testing (non-clinical)

The following non-clinical performance testing standards have been met for the IFM Surgical Mask Model SM3:

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
16 CFR Part 1610	Standard for the Flammability of Clothing
ISO 10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
ISO 10993-5	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity of medical devices
ISO 10993-10	Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization

Performance Testing (clinical)

No Clinical performance testing conducted.

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.