August 19, 2020

PFM Medical, Inc
Jessica Jho
Director of Regulatory Affairs
1916 Palomar Oaks Way, Suite 150
Carlsbad, California 92008

Re: K201137
Trade/Device Name: Asept Surgical Face Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: July 19, 2020
Received: July 23, 2020

Dear Jessica Jho:

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,

CAPT Elizabeth Claverie, M.S.
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)*

Device Name
Asept Surgical Face Mask

K201137

Indications for Use *(Describe)*
The ASEPT® Surgical Face Mask is indicated as a protective nose and mouth covering for healthcare workers and patients involved in medical and surgical procedures. The masks are indicated in any procedure or situation where there is a risk of exposure to microorganisms and body fluids.

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

K201137

As required by 21CFR 807.92
Date of Preparation: July 19, 2020

Applicant Information

510(k) Applicant: PFM Medical, Inc.
Applicant Address: 1916 Palomar Oaks Way, Suite 150, Carlsbad, CA 92008
Contact Person: Jessica Jho, RAC
Email: JJho@pfmmedicalusa.com

Device Information

Trade Name: ASEPT® Surgical Face Mask
Common Name: Mask, Surgical
Classification Name: Surgical Apparel
Product Code: FXX
Regulation Number: 21 CFR §878.4040

Predicate Device Information

Trade Name: Surgical Masks
Premarket Notification: K111559
Product Code: FXX,
Regulation Number: 21 CFR §878.4040
Manufacturer: Shanghai Neo-Medical Import & Export Co.

Device Description

ASEPT® Surgical Face Mask is a single-use, three layer, flat-folded mask with ear loops and nose piece. The inner and outer layers are constructed of spun-bond polypropylene and the middle layer is constructed of melt blown polypropylene filter. The mask is held in place over the mouth and nose by two elastic loops welded to the facemask. The elastic loops are not made with natural rubber latex. The nose piece is made of malleable polyethylene with aluminum wire and allows the user to fit the facemask around their nose. The ASEPT® Surgical Face Mask is sold non-sterile and is intended to be a single use, disposable device.

Indications for Use

The ASEPT® Surgical Face Mask is indicated as a protective nose and mouth covering for healthcare workers and patients involved in medical and surgical procedures. The masks are indicated in any procedure or situation where there is a risk of exposure to microorganisms and body fluids.

Comparison of Technological Characteristics Between the Predicate and Subject Devices

The following is a summary of the technological characteristics of the ASEPT® Surgical Face Mask as compared to the predicate device. The subject and predicate devices are the identical devices manufactured by the identical supplier.

Items		Subject Device	Predicate Device	Comparison
Manufacturer		PFM Medical, Inc.	Shanghai Neo-Medical Import & Export Co.	N/A
510(k) Number		K201137	K111559	N/A
FDA Product Code		FXX	FXX	Identical
Indications for Use		The ASEPT® Surgical Face Mask is indicated as a protective nose and mouth covering for healthcare workers and patients involved in medical and surgical procedures. The masks are indicated in any procedure or situation where there is a risk of exposure to microorganisms and body fluids.	The Surgical Masks are indicated as a protective nose and mouth covering for healthcare workers and patients involved in medical and surgical procedures. The masks are indicated in any procedure or situation where there is a risk of microorganism and body fluid.	Identical with grammatical correction.
Materials	**Inner and Outer Layers**	Spun-bond polypropylene	Spun-bond polypropylene	Identical
	Middle Layer	Melt blown polypropylene filter	Melt blown polypropylene filter	Identical
	Ear loops	Polyester	Polyester	Identical
	Nose Piece	Malleable polyethylene with aluminum wire	Malleable polyethylene with aluminum wire	Identical
Dimensions		17.5cm length x 9.5cm height	17.5cm length x 9.5cm height	Identical
Mask Style		Pleated	Pleated	Identical
Design Features		Malleable nosepiece, flat pleated, elastic ear loops	Malleable nosepiece, flat pleated, elastic ear loops	Identical
Sterility		Non-sterile	Non-sterile	Identical
Use		Single Use, Disposable	Single Use, Disposable	Identical
Color		Blue and White	Blue and White	Identical
ASTM F2100 Level		Level 2	Level 2	Identical
Biocompatibility	**Cytotoxicity, ISO 10993-5:2009**	Non-cytotoxic	Non-cytotoxic	same
	Irritation, ISO 10993-10:2002	Non-irritating	Non-irritating	same
	Sensitization, ISO 10993-10:2002	Non-sensitizing	Non-sensitizing	same

Summary of Non-Clinical Testing

Per FDA document Guidance for Industry and FDA Staff: Surgical Masks – Premarket Notification [510(k)] Submissions, the below testing has been completed on the subject device:

Item	Standard	Acceptance Criteria	Results
Fluid Resistance Performance	ASTM F1862: Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood	At least 29 out of 32 specimens show passing results at 120 mmHg	All samples met the predetermined acceptance criteria.
Bacterial Filtration Efficiency	ASTM F2100-19: Standard Specification for Performance of Materials Used in Medical Face Masks	≥ 98%	All samples met the predetermined acceptance criteria.
Differential Pressure (Delta P)	ASTM F2100-19: Standard Specification for Performance of Materials Used in Medical Face Masks	< 6.0 mm H_2O/cm^2	All samples met the predetermined acceptance criteria.
Particulate Filtration Efficiency	ASTM F2100-19: Standard Specification for Performance of Materials Used in Medical Face Masks	≥ 98%	All samples met the predetermined acceptance criteria.
Flammability	21 CFR 1610	Class I, Does not Ignite	All samples met the predetermined acceptance criteria.
Cytotoxicity	ISO 10993-5: Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity	Non-cytotoxic	All samples met the predetermined acceptance criteria.
Irritation	ISO 10993-10: Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization	Non-irritating	All samples met the predetermined acceptance criteria.
Sensitization	ISO 10993-10: Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization	Non-sensitizing	All samples met the predetermined acceptance criteria.

Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(k) K201137, the ASEPT® Surgical Face Mask, is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K111559.