July 14, 2021

Lear Corporation
Ryan Facer
Product Development Engineer
1 Penn Dye St
Pine Grove, Pennsylvania 17963

Re: K201844
Trade/Device Name: Disposable Surgical Face Mask, Surgical Face Mask, Surgical Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: June 15, 2021
Received: June 16, 2021

Dear Ryan Facer:

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,

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)*
K201844

Device Name
Disposable Surgical Face Mask, Surgical Face Mask, Surgical Mask

Indications for Use *(Describe)*
The Surgical Face Mask is intended for single use by operating room personnel, patients, and other general healthcare workers to protect against the transfer of microorganisms, blood, bodily fluids, and particulates. This is a non-sterile, single use, disposable device.

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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5. 510(k) Summary Report

K201844

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

Date Prepared: 06/10/2021

5.1. Submitter's Identification

Guilford Performance Textiles by Lear
1 Penn Dye St
Pine Grove, PA 17963 USA

Contact Person: Ryan Facer
Telephone: (336) 341-8687
Email: rfacer@lear.com

5.2. Device & Regulatory Information

Trade Name: Disposable Surgical Face Mask, Surgical Face Mask, Surgical Mask
Model Number: 69005
Common Name: Surgical Mask
510(k) Number: K201844
Classification Name: Mask, Surgical
Classification: Class II
Product Code: FXX
Regulation Number: 21 CFR 878.4040

5.3. Predicate Device

Submitter: DemeTECH Corporation
510(k) Number: K201479
Device Name: DemeMASK Surgical Mask

5.4. Device Description:

The proposed Surgical Face Mask is a non-sterile, single-use, 3-layer mask with outer and inner facing layers comprised of white spun-bond polypropylene and a middle layer comprised of white melt blown polypropylene. The mask is secured to the user via nylon/spandex ear loops that are ultrasonically welded to the mask. This mask does not contain any natural rubber latex. The device also contains a nose wire made of a pliable steel strip, coated in polypropylene, that helps to form the mask around the user's nose.

The types of materials used in the proposed Surgical Face Mask are currently being used in legally marketed devices.

5.5. Contact

Type: Surface Device – Intact Skin
Contact Duration: Limited – Less than 24 hours

5.6. Intended Use

The Surgical Face Mask is intended for single use by operating room personnel, patients, and other general healthcare workers to protect against the transfer of microorganisms, blood, bodily fluids, and particulates. This is a non-sterile, single-use, disposable device.

5.7. Comparison to Predicate Device

5.7.1. Intended Use/Indications for Use

Proposed Surgical Face Mask (K201844)	Predicate Surgical Mask (K201479)	Comparison
The Surgical Face Mask is intended for single use by operating room personnel, patients, and other general healthcare workers to protect against the transfer of microorganisms, blood, bodily fluids, and particulates. This is a non-sterile, single use, disposable device.	The Disposable Surgical Face Masks are 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.	Intended use/ Indications for Use is the same as the predicate device

5.7.2. Materials, Technical Specifications, & Risks to Health

Description		Proposed Surgical Face Mask (K201844)	Predicate Surgical Mask (K201479)	Comparison
Materials	Inner Layer	Spun-bond polypropylene	Spun-bond polypropylene	Same as the predicate device
	Middle Layer	Melt blown polypropylene	Melt blown polypropylene	Same as the predicate device
	Outer Layer	Spun-bond polypropylene	Spun-bond polypropylene	Same as the predicate device
	Nose Wire	Galvanized steel wire coated with polypropylene	Galvanized wire coated with polyethylene	Similar to the predicate device

	Elastic ear-loops	Nylon & spandex	Nylon & spandex	Same as the predicate device
Specifications	Mask Style	Flat Pleated	Flat pleated	Same as the predicate device
	Design Feature	Ear loops (Length: 150 mm)	Ear loops (Length: not provided)	Similar to predicate device
	Nose Wire	Length: 110 mm	Info not provided	Similar to predicate device
	Mask Dimensions	Length – 6.89 in Width – 3.74 in	Length – 6.89 in Width – 3.74 in	Same as the predicate device
Performance test results	Fluid Resistance ASTM 1862 (160 mmHg)	Pass	Pass	Same as the predicate device
	Particulate Filtration Efficiency ASTM F2299 (0.1 micron)	Avg. 99.0%	≥99%	Similar to the predicate device
	Bacterial Filtration Efficiency ASTM F2101	Avg. 99.1%	≥99%	Similar to the predicate device
	Differential Pressure ASTM F2100-19	Avg. 4.9 mmH_2O/cm^2	*Avg. 3.6 mmH_2O/cm^2	Similar to predicate device
	Flammability 16 CFR Part 1610	Class 1	Class 1	Same as the predicate device
	Biocompatibility ISO 10993-5 & ISO 10993-10 (Cytotoxicity, Irritation, Sensitization)	Pass	Pass	Same as the predicate device

*Predicate device was tested per MIL-M36954C.

5.8. Summary of Nonclinical Testing

The proposed Surgical Face Masks have been tested according to ASTM F2100-19, the relevant standards which comprise ASTM F2100-19, and ISO 10993 in order to determine substantial equivalence. The following tests were conducted on the proposed Surgical Face Masks:

I. ASTM F1862 Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity)

II. ASTM F2101 Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of *Staphylococcus aureus*
III. ASTM F2299 Test Method for Determining the Initial Efficiency of Materials Used in Medical Face Masks to Penetration by Particulates Using Latex Spheres
IV. EN 14683:2019, Annex C Method for Determination of Breathability (Differential Pressure)
V. 16 CFR Part 1610 Standard for the Flammability of Clothing Textiles
VI. ISO 10993-5 Biological Evaluation of Medical Devices – Part 5: Tests for In Vitro Cytotoxicity
VII. ISO 10993-10 Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization

All results of testing met ASTM F2100-19 level 3 acceptance criteria.

5.9. Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(K) submission K201844, the Surgical Face Mask, is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K201479.