March 24, 2023

Medline Industries, LP
Kelsey Closen
Regulatory Affairs Specialist
Three Lakes Drive
Northfield, Illinois 60093

Re: K223236
Trade/Device Name: Medline Surgical Face Mask and Medline Procedural Face Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: February 3, 2023
Received: February 22, 2023

Dear Kelsey Closen:

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,

Katherine D. Kavlock -S

for
Brent Showalter, Ph.D.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic 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)*
K223236

Device Name
Medline Surgical Face Mask and Medline Procedural Face Mask

Indications for Use *(Describe)*
The Medline Surgical Face Mask and Medline Procedural Face Mask are intended to be worn to protect both the patient and the healthcare worker from the 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. These masks are single use, disposable, non-sterile devices.

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
[AS REQUIRED BY 21CFR807.92(c)]

Submitter / 510(k) Sponsor
Medline Industries, LP
Three Lakes Drive
Northfield, IL 60093

Registration Number: 1417592

Contact Person
Contact Person: Kelsey Closen, Regulatory Affairs Specialist
Phone: 847-949-2283
Email: KClosen@medline.com

Summary Preparation Date
October 7, 2022

Type of 510(k) Submission
Traditional

Device Name / Classification
Trade Name: Medline Surgical Face Mask and Medline Procedural Face Mask
Common Name: Surgical Mask
Classification Name: Mask, Surgical
Product Code: FXX
Classification Panel: Orthopedic
Regulatory Class: II
Regulation Number: 21 CFR 878.4040

Predicate Device
K202598: Surgical Masks with Ear Loops or Ties, Level 1, Level 2, Level 3

Device Description
The Medline Surgical Face Mask and Medline Procedural Face Mask are single-use, disposable device, provided non-sterile. Depending on the configurations, the Medline Surgical Face Mask and Medline Procedural Face Mask are composed of three or four layers of nonwoven materials: an outer layer, middle filtration layer(s) and an inner facing layer. The outer/inner facing layers are constructed of non-woven fabric and the middle filtration layer(s) are constructed of melt blown non-woven fabric.

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Each mask contains tie strings or ear loops to secure the mask over the user's face and mouth, and come in a flat pleated style that includes a malleable nosepiece to provide a firm fit over the nose. The Medline Surgical Face Mask and Medline Procedural Face Mask may also come equipped with an anti-fog foam stripe, anti-glare stripe and/or a face shield to cover the upper part of the face. The Medline Surgical Face Mask and Medline Procedural Face Mask may also be provided in an ASTM Fluid level of Level 1, Level 2 or Level 3. The color of the facemasks will be available in white, yellow, blue, or pink stripes.

Indications for Use

The Medline Surgical Face Mask and Medline Procedural Face Mask is intended to be worn to protect both the patient and the healthcare worker from the 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. These masks are single use, disposable, non-sterile devices.

Summary of Technological Characteristics

TABLE 1: COMPARISON OF PROPOSED AND PREDICATE DEVICES

Device Characteristic	Proposed Device	Predicate Device	Comparison Analysis
Product Name	Medline Surgical Face Mask and Medline Procedural Face Mask	Surgical Masks with Ear Loops or Ties, Level 1, Level 2, Level 3	N/A
510(k) Reference	TBD	K202598	N/A
Product Owner	Medline Industries LP	3A Medical Products Co., Ltd	N/A
Regulation Number	878.4040	878.4040	Same
Product Code	FXX	FXX	Same
Intended Use	This mask is intended to be worn to protect both the patient and the healthcare worker from the 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. These masks are single use, disposable, non-sterile devices	This mask is intended to be worn to protect both the patient and healthcare worker from the transfer of microorganisms, body fluids and Particulate material. This mask is intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This is a single use device provided nonsterile.	Same
Design Features	Pleated Nose Piece	Pleated Nose Piece	Similar-Additionally

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	Face Shield Anti-glare strip Anti-fog foam strip Ties Ear loops	Ties Ear loops	Medline offers the facemask in a face shield, anti-glare and anti- fog style. There are no safety or risk concern with these optional features.
Color Configurations	Blue Yellow White Pink Stripe	Blue	Similar – Medline offers the facemasks in more colors. There is no safety or risk concern with the additional colors based on biocompatibility testing
Materials	Face Mask: 1. Spunbond/Meltblown/Spunbond 2. Cellulose/Meltblown/Spunbond 3. Cellulose/Meltblown/Cellulose 4. Cellulose/Meltblown Spunbond/Cellulose 5. Thermalbond/Meltblown/Spunbond Ear Loops: 1. PP& Lycra 2. Polyester & Spandex 3. Polypropylene 4. Polyester, Spandex & Urethane Ties: 1. PP Nose Strip: 1. HDPE, Paper, Wire 2. Polypropylene & iron 3. Aluminum 4. Iron & PE 5. Steel & PE	Face Mask: 1. Polypropylene/Spunbond/Polypropylene 2. Polypropylene/Meltblown/Polypropylene Ear Loops: 1. Polyester/Spandex Ties: 1. Polypropylene Spunbond Nose Strip : 1. Polyethylene coated Steel Wire	Similar – Medline offers more fabric variations but there is no safety or risk concern based on performance and biocompatibility testing
Prescription vs. OTC	OTC	OTC	Same

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Sterile vs. Non-Sterile	Non-Sterile	Non-Sterile	Same
Disposable vs. Non-Disposable	Disposable	Disposable	Same
Single Use vs. Reusable	Single Use	Single Use	Same
ASTM F2100 Level	Level 1, 2, 3	Level 1, 2, 3	Same

Summary of Non-Clinical Testing

Non-clinical performance testing was completed on the Medline Surgical Face Mask and Medline Procedural Face Mask to demonstrate the safety and effectiveness of the subject device in accordance with the relevant test methods described in **Table 2** below.

Table 2: Non-Clinical Performance Testing Standards

ISO 10993-5	ISO MEM Elution Using L-929 Mouse Fibroblast Cells
ISO 10993-10	Repeated Patch Dermal Sensitization Test
ISO 10993-10	ISO Intracutaneous Irritation Test
ISO 10993-1	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
ASTM F2101-19	Bacterial filtration efficiency (BFE)
ASTM F1862	Resistance to penetration by synthetic blood
16 CFR Part 1610	Standard for the Flammability of Clothing
ASTM F2100	Standard Specification for Performance of Materials Used in Medical Face Masks
EN 14683:2019	Differential Pressure (Delta-P)
ASTM F2299	Sub-micron particulate filtration efficiency (PFE)

Summary of Clinical Testing

Not applicable.

Conclusion

In accordance with 21 CFR Part 807, and based on the information provided in this premarket notification, Medline Industries, LP. concludes that the Medline Surgical Face Mask and Medline Procedural Face Mask are as safe and as effective for their intended use as the predicate device, Surgical Masks with Ear Loops or Ties, Level 1, Level 2, Level 3 (K202598).