August 3, 2021

Esstee Exports Health Care Division
℅ Amy Fowler
Regulatory Counsel
Pathmaker FDA Law, PLLC
901 Twelve Oaks Center Drive
Wayzata, Minnesota 55391

Re: K210761
Trade/Device Name: Velguard Surgical Face Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical apparel
Regulatory Class: Class II
Product Code: FXX

Dear Amy Fowler:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated July 16, 2021. Specifically, FDA is updating this SE Letter as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Clarence W. Murray III, OHT4: Office of Surgical and Infection Control Devices, 301-796-0270, Clarence.Murray@fda.hhs.gov.

Sincerely,

Liqun Zhao -S

For Clarence W. Murray III, Ph.D.
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

July 16, 2021

Estee Exports Health Care Division
% Amy Fowler
Regulatory Counsel
Pathmaker FDA Law, PLLC
901 Twelve Oaks Center Drive
Wayzata, Minnesota 55391

Re: K210761
Trade/Device Name: Velguard Surgical Face Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical apparel
Regulatory Class: Class II
Product Code: FXX
Dated: June 11, 2021
Received: June 14, 2021

Dear Amy Fowler:

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 -S

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)*
K210761

Device Name
Velguard Surgical Face Mask

Indications for Use *(Describe)*
The Velguard Surgical Face 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 the potential exposure to blood and body fluids. This is a 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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

ESSTEE EXPORTS
HEALTH CARE DIVISION

510(k) Summary

Velguard Surgical Face Mask (K210761)

Sponsor Information:	Esstee Exports Health Care Division 8/3176 A3 & A4, Jothipuram, 2nd Street, Pandian Nagar, PN Road, Tirupur, Tamil Nadu, India 641602 Sponsor Contact: Zachary Wilson Lacote Supply, Inc. 880 N Ventura Ave, Ste G Oak View, CA 93022 Em: zwilson@lacotesupply.com Ph: 805-365-1348
Contact Person:	Amy Fowler Regulatory Counsel Pathmaker FDA Law, PLLC 901 Twelve Oaks Center Drive Suite 936 Wayzata, Minnesota 55391 Em: fowler@pathmakerlaw.com Ph: 612-356-9653
Date of Summary Preparation:	June 11, 2021
Proprietary Name:	Velguard Surgical Face Mask, Model Number VG3MCB
Common Name:	Surgical Mask
Device Classification:	Class II
Classification Name:	Surgical Apparel
Regulation Medical Specialty:	General and Plastic Surgery
Review Panel:	General Hospital
Product Code:	FXX
Regulatory Class:	Class II
Predicate Device:	Surgical Face Mask (K182515) - Model Ear Loop (no known design-related recalls)

Device Description:

The Velguard Surgical Face Mask is a single use, three pleated, flat–folded rectangular masks with ear loops and adjustable nose wire. The Surgical Masks are manufactured with three layers, the inner and outer layers are made of spun-bond polypropylene, and the middle layer is made of melt blown polypropylene filter. The inner spun-bond polypropylene layer uses no colorant. The outer spun-bond polypropylene layer uses a blue colorant. The ear loops are held in place over the users' mouth and nose by two elastic ear loops welded to the facemask. The elastic ear loops are not made with natural rubber latex. The nose piece in the layers of facemask is to allow the user to fit the facemask around their nose, which is made of malleable polyethylene coated zinc wire. The surgical face masks are sold non-sterile and are intended to be single use, disposable devices.

Intended Use/Indications for Use:

The Velguard Surgical Face 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 the potential exposure to blood and body fluids. This is a single use, disposable device, provided non-sterile.

Comparison of Subject and Predicate Devices:

Item(s)	**Subject Device (K210761)** Velguard Surgical Face Mask	**Predicate Device (K182515)** Surgical Face Mask	**Comparison**
Intended Use / Indications for Use	The Velguard Surgical Face 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 the potential exposure to blood and body fluids. This is a single use, disposable device, provided non-sterile.	The 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(s), provided non-sterile	**Same, minor differences to correct grammar.**
Type of Use	Over-The-Counter Use (21 CFR 801 Subpart C)	Over-The-Counter Use (21 CFR 801 Subpart C)	**Same**
Outer facing layer	Spun-bond polypropylene	Spun-bond polypropylene	**Same**
Middle layer	Melt blown polypropylene filter	Melt blown polypropylene filter	**Same**

Item(s)	**Subject Device (K210761)** Velguard Surgical Face Mask	**Predicate Device (K182515)** Surgical Face Mask	Comparison
Inner facing layer	Spun-bond polypropylene	Spun-bond polypropylene	**Same**
Nose piece	Malleable polyethylene coated zinc wire	Malleable polyethylene wire	**Similar, both nose pieces use malleable polyethylene. The subject device nose piece is enclosed within the layers.**
Ear loops	Polyester spandex blend	Spandex	**Similar, both use spandex for elasticity.**
Color(s)	Blue & White	Yellow	**Different, the difference in colorants does not raise concerns of safety or effectiveness. Biocompatibility testing demonstrated the subject device was non-cytotoxic, non-irritating, and non-sensitizing.**
Mask Style	Flat Pleated	Flat Pleated	**Same**
Length	17.5cm ±0.5cm	17.5cm±0.2cm	**Similar**
Width	9.5cm ±0.3cm	9.5cm±0.2cm	**Similar**
Sterile	Non-Sterile	Non-Sterile	**Same**
Use	Single Use	Single Use	**Same**
Performance Testing	Level 3 - ASTM F2100-19	Level 2 - ASTM F2100-11	**Different, subject devices exceeded predicate device in one performance test. ASTM F2100-19 uses different test method for measuring Delta-P (H_2O/cm^2).**

Item(s)	**Subject Device (K210761)** Velguard Surgical Face Mask	**Predicate Device (K182515)** Surgical Face Mask	**Comparison**
Fluid Resistance Performance	Three lots passed at 160mm Hg – ASTM F1862	32/32 passed at 120 mmHg - ASTM F1862	**Similar, subject device exceeded fluid resistance of the predicate device.**
Particulate Filtration Efficiency	Three lots passed at ≥98% @ 0.1 micron – ASTM F2299	pass at 99.7% - ASTM F2299	**Similar, both devices meet ASTM F2299.**
Bacterial Filtration Efficiency	Three lots passed at ≥98% – ASTM F2101	pass at 99.9% - ASTM F2101	**Similar, both devices meet ASTM F2101.**
Differential Pressure	Three lots passed at <5 Delta-P (mmH2O/cm2) – EN 14683:2019, Annex C and ASTM F2100-19	4.0mmH_2O/cm^2 - MIL-M-36954C	**Similar, subject device utilized ASTM F2100-19 test methods (FR Recognition Number 6-425).**
Flammability	Three lots passed – Class 1 16 CFR 1610	Class 1 16 CFR 1610	**Same**
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**

Differences in technological characteristics do not raise different questions of safety and effectiveness.

Summary of Non-Clinical Performance Testing:
Non-clinical tests were conducted on 32 samples per lot, three non-consecutive lots. The tests were in accordance with the recommendations included in the *Guidance for Industry and FDA Staff: Surgical Masks – Premarket Notification [510(k)] Submission* issued on March 5, 2004 and the following FDA recognized consensus standards:

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
EN 14683	Standard Test Method for Differential Pressure
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

Summary of Clinical Performance Test:
No clinical study is included in this submission.

Conclusion:
The conclusions drawn from the nonclinical tests demonstrate that the proposed subject device K210761 is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K182515.