November 23, 2020

Shenzhen Everwin Precision Technology Co., Ltd.
% Olivia Meng
Regulatory Affairs Manager
Guangzhou Osmunda Medical Device Technical Services Co. Ltd.
8-9th Floor, R&D Building, No.26 Qinglan Street,
Panyu District
Guangzhou, Guangdong 510006
China

Re: K201991
Trade/Device Name: Medical surgical mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical apparel
Regulatory Class: Class II
Product Code: FXX
Dated: July 10, 2020
Received: July 17, 2020

Dear Olivia Meng:

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 and Part 809); 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 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K201991

Device Name
Medical surgical mask

Indications for Use *(Describe)*
The medical surgical mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids, and particulate material. This face mask is 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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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."

510(k) Summary
K201991

1. SUBMITTER

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Date prepared	November 23, 2020

2. DEVICE

Trade Name:	Medical SurgicalMask
Common name:	Surgical Mask
Model:	EWPT0005
Classification name	Mask, Surgical
Regulation number	21 CFR 878.4040
Regulation Class:	Class II
Product Code:	FXX

3. PREDICATE DEVICE

K160269, Surgical Face Masks (Ear loops and Tie-on)

4. DEVICE DESCRIPTION

The medical surgical mask is designed and manufactured by Shenzhen Everwin

Precision Technology Co, Ltd. It is non-sterile and for single use. It's a disposable device. The medical surgical mask is manufactured with three-layers, the inner and outer layers are made of polypropylene, and the middle layer is made of melt blown polypropylene. The elastic ear loop of proposed device is made of spandex and nylon, not made with natural rubber latex. The nose piece contained in the proposed device allows the user to fit the face mask around their nose, which is made from steel wire.

5. INDICATIONS FOR USE

The medical surgical mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids, and particulate material. This face mask is 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.

6. Summary of Technological Characteristics

Comparison Item	Proposed device	Predicate device	Comparison result
510k number	K201991	K160269	-
Intended Use	The medical surgical mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids, and particulate material. This face mask is 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, provided non-sterile.	Same
Mask style	Flat pleated	Flat pleated	Same
Design feature	Ear loop	Earloop or tie-on	Similar
Material of outer facing layer	Polypropylene	Polypropylene	Same
Material of middle layer	Melt blown polypropylene	Polypropylene meltblown and polypropylene	Similar

		spunbond	
Material of inner facing layer	Polypropylene	Polypropylene	Same
Nosepiece	Polypropylene coated steel wire	Polypropylene steel wire coated	Same
Attachment	Ear loops: Spandex and nylon	Ear loops: Polyester, polyurethane Side tapes: Polyester spunbond (ear loops mask only) Tie tapes: Polypropylene spunbondor polyester spunbond	Similar
Dimension (Length × Width)	17.5 cm × 9.5 cm	17.5 cm × 9.0 cm 18.0 cm × 9.0 cm	Similar
OTC use	Yes	Yes	Same
Sterility	Non-sterile	Non-sterile	Same
Single use	Yes	Yes	Same
ASTM F 2100 level	Level 3	Level 1 Level 2 Level 3	Similar
Biocompatibility	Pass ISO 10993cytotoxicity, skin irritation and skin sensitivity tests	Pass ISO 10993cytotoxicity, skin irritation and skin sensitivity tests	Same

The subject device is the same as the predicate device in the intended use, material, ASTM F2100 level and biocompatibility, and similar in mask style, design feature and dimension. So the subject device is identical to the predicate device.

7. PERFORMANCE DATA

7.1. Non-clinical test performed on the proposed device

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

The biocompatibility evaluation for the medical surgical mask was conducted in accordance with the International Standard ISO 10993-1:2018, "Biological evaluation of

medical devices - Part 1: Evaluation and testing within a risk management process" as recognized by FDA. The biocompatible testing included the following tests:

Item	Acceptance Criteria	Proposed device	Predicate device	Result
Cytotoxicity	Under the conditions of the study, the subject device was non-cytotoxic.	Under the conditions of the study, the subject device was non-cytotoxic.	Under the conditions of the study, the subject device was non-cytotoxic	Same
Sensitization	Under the conditions of the study, the subject device was non-sensitizing	Under the conditions of the study, the subject device was non-sensitizing.	Under the conditions of the study, the subject device was non-sensitizing.	Same
Skin Irritation	Under the conditions of the study, the subject device was non-irritating.	Under the conditions of the study, the subject device was non-irritating.	Underthe conditions of the study, the subject device was non-irritating.	Same

Performance testing

Performance testing was conducted on the medical surgical mask. All of the tested parameters met the predefined acceptance criteria.

Item	Proposed device	Predicate device	Acceptance Criteria	Result
Flammability	Class I	Class I	Class I	Same
Bacterial Filtration Efficiency	>=98%	98%	>=98%	Same

Item	Proposed device	Predicate device	Acceptance Criteria	Result
Differential Pressure, mm H_2O/cm^2	<6.0 H_2O/cm^2 mm	Pass at average 5.5 mm H_2O/cm^2	<6.0 H2O/cm2 mm	Similar
Sub-Micron Particle Filtration Efficiency	>= 98%	Average 99.8%	>= 98%	Similar
Resistance to Penetration by Synthetic Blood (mmHg)	29 out of 32 at passes 160mmHg	29 out of 32 passes at 160mmHg	29 out of 32 passes at 160mmHg	Same

7.2. Clinical test conclusion

No clinical study is included in this submission.

8. CONCLUSION

8.1. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate device, Surgical Face Mask (K160269).