July 2, 2021

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

Re: K203591
Trade/Device Name: Single-use Medical Face Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: May 6, 2021
Received: May 12, 2021

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); 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,

Clarence W. Murray, III, PhD
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)*
K203591

Device Name
Single-use Medical Face Mask

Indications for Use *(Describe)*
The Single-use Medical 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.

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."

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

1. SUBMITTER

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Primary Contact Person:	Olivia Meng Regulatory Affairs Manager Guangzhou Osmunda Medical Device Technical Service Co., Ltd. Tel: (+86)-20-6231 6262 Fax: (+86)-20-8633 0253
Secondary Contact Person:	Ms. Carrie Wu Compliance Director Conod Medical Co., Limited Phone: +86-0512-52306320 Fax: +86-0512-52301831
Date prepared	May 6th, 2021

2. DEVICE

Device Name:	Single-use Medical Face Mask
Common name:	Mask, Surgical
Model:	Earloop: ARR-DMM-175-50 ARR-DMM-165-50 ARR-DMM-145-50 Tie Coverall: ARR-DTM-175-50
Regulation number	21 CFR 878.4040
Regulation Class:	II
Product Code:	FXX

3. PREDICATE DEVICE

K202719, Disposable Medical Face Masks

This predicate has not been subject to a design-related recall.

4. DEVICE DESCRIPTION

The Single-use Medical Face Mask is designed and manufactured by Conod Medical Co., Limited. It is non-sterile and for single use.

The Single-use Medical Face Mask has two models, Earloop and Tie Coverall. It is made of three-layer nonwovens, ear loops (for Earloop model)/ tie tapes (for Tie Coverall model) and nose piece. Inner and outer layers are made of spun-bond polypropylene, and the middle layer is made of melt blown polypropylene filter. The ear loops/ tie tapes are held in place over the users' mouth and nose by two elastic ear loops/ tie tapes welded to the mask. The ear loops are made of polyester, and the tie tapes are made of spun-bond polypropylene. The nose piece in the layers of mask is to allow the user to fit the mask around their nose, which is made of malleable aluminum wire.

It is a self-inhalation filter mask, which works by filtering the air containing harmful substances through the filter material of the mask before being inhaled or exhaled.

The product is level 2 according to ASTM F2100-19. The main parameters of the product are listed as followed:

- Bacterial filtration efficiency (BFE) ≥ 98%
- Sub-micron particle filtration efficiency ≥ 98%
- Different pressure: < 6.0 mm H_2O/cm^2
- Flammability: class 1
- Resistance to penetration by synthetic blood: 120 mmHg

5. INDICATIONS FOR USE

The Single-use Medical 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.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Item	Proposed device	Predicate device	Comparison result
Manufacturer	Conod Medical Co., Limited	Jiangxi Sanxin Medtec Co., Ltd.	NA
510K Number	K203591	K202719	NA

Product Common Name	Single-use Medical Face Mask	Disposable Medical Face Masks	NA
Intended Use	The Single-use Medical 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.	The non-sterile disposable medical 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	Earloop, Tie Coverall, 3 layers	Ear-loop, Tie-on, 3 layers	Same
Material of outer facing layer	Spun-bond polypropylene	Polypropylene non-woven fabric	Similar
Material of middle layer	Melt blown polypropylene filter	Melt-blown polypropylene	Same
Material of inner facing layer	Spun-bond Polypropylene	Polypropylene non-woven fabric	Similar
Nose piece	Malleable aluminum wire	Galvanized iron wire coated with polypropylene	Different
Attachment	Ear loops: Polyester	Ear strap (ear-loop): Polyester and spandex	Similar
	Tie tapes: Spun-bond Polypropylene	Ear strap (tie-on): Polypropylene non-woven fabric	
Color	Blue	Blue	Same
Dimension (Length × Width)	Earloop: 17.5 cm × 9.5 cm 16.5 cm × 9.0 cm 14.5 cm × 9.5 cm Tie Coverall: 17.5 cm × 9.5 cm	Ear-loop: 17.5 cm × 9.5 cm 16.0 cm × 9.5 cm 15.5 cm × 9.5 cm 14.5 cm × 9.5 cm 14.0 cm × 9.5 cm Tie-on: Same as above	Similar
OTC use	Yes	Yes	Same
Sterility	Non-sterile	Non-sterile	Same

Single use	Yes	Yes	Same
ASTM F 2100 level	Level 2	Level 2	Same
Fluid Resistance Performance ASTM F1862	32 out of 32 pass at 120 mmHg	Pass at 120 mmHg	Same
Particulate Filtration Efficiency ASTM F2299	Average 99.80%	98.17%	Similar
Bacterial Filtration Efficiency ASTM F2101	Average 99.77%	98.38%	Similar
Differential Pressure (Delta P) ASTM F2100	Average 4.01 mmH_2O/cm^2	1.78 mmH_2O/cm^2	Similar
Flammability 16 CFR 1610	Class 1 Non-Flammable	Class 1 Non-Flammable	Same
Biocompatibility			
Cytotoxicity	Under the conditions of the study, not cytotoxic	Under the conditions of the study, not cytotoxic	Same
Irritation	Under the conditions of the study, not an irritant	Under the conditions of the study, not an irritant	Same
Sensitization	Under conditions of the study, not a sensitizer	Under conditions of the study, not a sensitizer	Same

The proposed Single-use Medical Face Mask and the predicate device are identical in the intended use, mask style, design feature, material, ASTM F2100 level and biocompatibility, and similar only in dimension and some components material.

7. PERFORMANCE DATA

The following performance data demonstrated in 3 non-consecutive lots were provided demonstrate that the subject device met the specification found in the standard. The results demonstrated that the subject device meets the acceptance criteria found in the standard.

Test item		Test purpose	Acceptance criteria	Results
Performance test	Flammability	Testing the characteristics of a material that pertain to its relative ease of ignition and relative ability to sustain co mbustion.	Class 1 ASTM F2100 3 non-consecutive lots, 32 samples per lot	Pass
	Bacterial Filtration Efficiency	Testing the effectiveness of medical face mask material in preventing the passage of aerosolized bacteria.	Level 2: ≥ 98% ASTM F2100 3 non-consecutive lots, 32 samples per lot	Pass
	Different Pressure, mm H_2O/cm^2	Measuring the pressure of dropping across a medical face mask material.	Level 2: < 6.0 ASTM F2100 3 non-consecutive lots, 32 samples per lot	Pass
	Sub-Micron Particle Filtration Efficiency	Testing the efficiency of the filter material in capturing aerosolized particles smaller than one micron.	Level 2: ≥ 98% ASTM F2100 3 non-consecutive lots, 32 samples per lot	Pass
	Resistance to Penetration by synthetic blood	Testing the efficiency of resistance to penetration by synthetic blood.	Level 2: pass at 120 mmHg ASTM F2100 3 non-consecutive lots, 32 samples per lot	Pass
Biocompatibility	Cytotoxicity	Determining the cytotoxicity of proposed device.	Pass	
	Sensitization	Determining whether the proposed device has sensitization potential.	Pass	
	Skin Irritation	Determining whether the proposed device has irritation potential.	Pass	

8. CONCLUSION

The conclusions drawn from the nonclinical tests demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device.