August 26, 2020

Modern Healthcare Corp.
℅ Ke-Min Jen
Contact Person
Chinese European Industrial Research Society
No. 58, Fu-Chiun St
Hsin-Chu City, Taiwan 30067
Taiwan

Re: K201549
Trade/Device Name: Motex Anti-Fog Surgical Face Mask, type: Tie-on, Ear-loop
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: June 2, 2020
Received: June 9, 2020

Dear Ke-Min Jen:

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,

For Elizabeth Claverie
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201549

Device Name
Motex Anti-Fog Surgical Face Mask, type: Tie-on, Ear-loop

Indications for Use *(Describe)*
The Motex Anti-Fog 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 potential exposure to blood and body fluids. The face mask is 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.

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510(K) Summary

Submission Date: 08/22/2020

K201549

SUBMITTER INFORMATION:

Company Name: Modern Healthcare Corp.

Company Address: No. 751, Sec. 2, Chung Chou Rd., Tien Chung Town,
Chang-Hwa County, 52045, Taiwan

Contact Person: Dr. Jen, Ke-Min
Phone: + 886-4-8752116
ceirs.jen@msa.hinet.net

Device Trade Name: Motex Anti-Fog Surgical Face Mask, type: Tie-on, Ear-loop

Device Common Name: Surgical Mask

Class: Class II

Classification: 21 CFR 878.4040
Surgical Mask

Product Code: FXX

Predicate Devices:

Surgical Face Mask, type: Tie-on, Ear-loop K063043, Modern Healthcare Corp.

Device Description:

The Motex Anti-Fog Surgical Face Mask, type: Tie-on, Ear-loop, is flat pleated 3-ply device, which consists of four layers, i.e., Inner layer (Bicomponent thermal-bonded nonwoven, Polypropylene / Polyethylene, PP/PE), Filter layer (Polypropylene Melt-blown), Outer layer (Polypropylene Spunbond, blue/ green/ white/ pink color) and Anti-Fog films (EP coated Polyethylene). Each mask contains tie-on strips or elastic ear loops and nose band of steel wire coated with Polyethylene resin to secure the mask fit over the user's mouth and nose. The dimensions of each mask are length 165±5 mm and width 95±2 mm.

Indications for Use:

The Motex Anti-Fog 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 potential exposure to blood and body fluids. The face mask is single use, disposable device, provided non-sterile.

Non-Clinical Tests Performed:

- Performance Testing summary

Test item (Performance Level 3)	Test method	Pass criteria	Test results /Verdict
Bacterial filtration efficiency	ASTM F2101-14	≥ 98%	≧99% / Pass
Differential pressure (Delta-P)	MIL-M-36954C, Section 4.4.1.2	< 5 mm H_2O/cm^2	2.6 mm H_2O/cm^2 / Pass
Sub-micron particulate filtration efficiency at 0.1 μm of Polystyrene Latex Spheres	ASTM F2299-03	≥ 98%	99.75% / Pass
Resistance to penetration by synthetic blood, minimum pressure in mm Hg for pass result	ASTM F1862-17 ISO 22609:14	Fluid resistant claimed at 80, 120, 160 mm Hg	Fluid Resistant claimed at 160 mm Hg / Pass
Flame spread	16 CFR Part 1610	Class 1	Class 1 / Pass

- Biocompatibility Testing

According to ISO 10993-1:2009, the nature of body contact for the subject device is Surface Device category, Skin Contact and duration of contact is A-Limited (≦24h). The following tests for the subject device were conducted to demonstrate that the subject device is biocompatible and safe for its intended use:

1) In vitro Cytotoxicity Test per ISO 10993-5:2009 Biological evaluation of medical devices- Part 5: Tests for in vitro cytotoxicity,
2) Skin Sensitization Tests per ISO 10993-10:2010 Biological evaluation of medical devices— Part 10: Tests for irritation and skin sensitization,
3) Skin Irritation Tests per ISO 10993-10:2010 Biological evaluation of medical devices— Part 10: Tests for irritation and skin sensitization.

Clinical Tests Performed:

No clinical trials were conducted.

Description	Subject device	Predicate device	Comparison result
510(k) number	K201549	K063043	--
Product trade name	Motex Anti-Fog Surgical Face Mask, type: Tie-on, Ear-loop	Surgical Face Mask type: Tie-on, Ear-loop	Similar
Manufacturer	Modern Healthcare Corp.	Modern Healthcare Corp.	Same
Classification name	MASK, SURGICAL	MASK, SURGICAL	Same
Product Code	FXX	FXX	Same
Device Class	2	2	Same
Regulation number	878.4040	878.4040	Same
Indications for Use	The Motex Anti-Fog 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 potential exposure to blood and body fluids. The face mask is single use, disposable device, provided non-sterile.	The surgical face mask of different colors (green, white, blue and pink) is a device intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operation room personnel from transfer of microorganisms, body fluid and particulate material.	Same
Material composition	Inner layer: Bicomponent thermal-bonded nonwoven (PP/PE) Filter layer: Polypropylene Melt-blown Outer layer: Polypropylene Spunbond (blue, green, white, pink color) Anti-Fog film: EP coated Polyethylene Nose band: Steel wire coated with Polyethylene resin Ear loop: Spandex Tie strip: Polypropylene Spunbond	Inner layer: Polypropylene Spunbond Filter layer: Polypropylene Melt-blown Outer layer: Polypropylene Spunbond (blue, green, white, pink color) Nose band: malleable aluminum wire Ear loop: Spandex Tie strip: Polypropylene Spunbond	Similar
Anti-Fog function	Yes	No	Different
Dimensions	Length: 165±5 mm Width: 95 ±2 mm	Length: 165±5 mm Width: 95 ±2 mm	Same
Mask style	Flat pleated	Flat pleated	Same
Design features	Ear-loop & Tie-on	Ear-loop & Tie-on	Same
Performance level 3 testing			
Fluid Resistance (mm Hg)	160	160	Same
Particulate Filtration Efficiency at 0.1 micron (%)	Average 99.75%	Average 96.8%	Different
Bacterial Filtration Efficiency (%)	Higher than 99%	Higher than 99%	Same

Differential Pressure (Delta-P) Test (mm H_2O/cm^2)	Average 2.6	Average 2.6	Same
Flame spread	Class 1 (No Flame Spread)	Class 1 (No Flame Spread)	Same
Biocompatibility testing			
In vitro Cytotoxicity Test	Pass ISO 10993-5:2009	Pass ISO 10993-5	Same
Skin Sensitization Test	Pass ISO 10993-10:2010	Pass ISO 10993-10	Same
Skin Irritation Test	Pass ISO 10993-10:2010	Pass ISO 10993-10	Same

Substantial Equivalence:

The subject device is the same as the predicate device with respect to the indications for use, product dimensions, mask style, design features, fluid resistance, bacterial filtration efficiency, differential pressure (Delta-P) test, and flame spread. The major differences between the new and the predicate devices are the material composition, the anti-fog function, and particulate filtration efficiency.

The differences of the material composition are inner layer and nose band. The inner layer is made of the bicomponent thermal-bonded nonwoven (PP/PE) to increase particulate filtration efficiency to 99.75%, which value is higher than 96.8% of the predicate device. By adding a film of EP coated polyethylene on the outer surface of outer layer, the new device can effectively decrease the fog formation on the user's glasses due to breath. The differences of materials mentioned above do not raise any new safety and effectiveness concerns for the subject device.

The biocompatibility data and the results of performance testing presented, demonstrate the substantial equivalence of the Motex Anti-Fog Surgical Face Mask to that of the legally marketed predicate device K063043.

Conclusion:

The conclusion drawn from the nonclinical tests demonstrates that the subject device the Motex Anti-Fog Surgical Face Mask in 510(k) K201549, is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K063043."