March 2, 2022

Medtecs (Taiwan) Corp.
% Sandy Liu
Consultant
Jin Services Co.
9F-1, No13, Lane41, Zhangrong Rd, Sec. 5, North District
Tainan City, 70447
Taiwan

Re: K203376
Trade/Device Name: ASTM Level 1/EN14683 Type IIR 3-Ply Disposable Surgical Mask, Model number: FM-1400G
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: February 7, 2022
Received: February 18, 2022

Dear Sandy Liu:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K203376

Device Name
ASTM Level 1/EN14683 Type IIR 3-Ply disposable Surgical Mask, Model number: FM-140G

Indications for Use *(Describe)*
ASTM Level 1/EN14683 Type IIR 3-Ply disposable Surgical Mask, Model number: FM-140G are intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids and particulate material. The face masks are 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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K203376

510(k) Summary

As required by 21CFR 807.92

Date of Preparation: 2020.10.30

Applicant Information

Company Name:	MEDTECS (TAIWAN) CORP.
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Telephone:	+886-2-27392222
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Contact Person:	William Yang
Summary Preparation Date:	2020.10.30

Official Correspondent

Company Name:	Jin Services Co.
Company Address:	9F-1, No13, Lane41, Zhangrong Rd, Sec. 5, North Distrit, Tainan City, Taiwan70447, Taiwan
Telephone:	+886-917535026
Email:	contact@fdaclass.com
Contact Person:	Sandy Liu, Consultant

Device Name:

Trade Name: ASTM Level 1/EN14683 Type IIR 3-Ply disposable Surgical Mask,

Model number: FM-140G

Classification Name:	Surgical Mask
Regulation Number:	878.4040
Product Code:	FXX
Device Class:	Class II
Panel:	General Hospital

PREDICATE DEVICE:

K123115, Surgical Face Mask with Ear-Loop, YN-50 JAG

Acme Filter Mask Inc.

REFERENCE DEVICE:

K200847, Avianz® Surgical Face Mask

MEXPO INTERNATIONAL INC.

Device Description

The ASTM Level 1/EN14683 Type IIR 3-Ply disposable Surgical Mask, Model number: FM-140G is a single-use, three layer, flat-folded mask with ear loops and nose piece. The inner and outer layers are constructed of spun-bond non-woven polypropylene and the middle layer is constructed of melt blown non-woven polypropylene. The mask is held in place over the 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 is made of malleable polyethylene with Galvanized
iron wire and allows the user to fit the facemask around their nose. The ASTM Level 1/EN14683 Type IIR 3-Ply disposable Surgical Mask, Model number: FM-140G is sold non-sterile and is intended to be a single use, disposable device.

Intended Use:

ASTM Level 1/EN14683 Type IIR 3-Ply disposable Surgical Mask, Model number: FM-140G are intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids and particulate material. The face masks are single use, disposable device, provided non-sterile.

Technological Characteristics Comparison

The following is a summary of the technological characteristics of the ASTM Level 1/EN14683 Type IIR 3-Ply disposable Surgical Mask, Model number: FM-140G as compared to the predicate device.

Items	**Subject Device** ASTM Level 1/EN14683 Type IIR 3-Ply disposable Surgical Mask, Model number: FM-140G	**Predicate Device** **Surgical Face Mask with Ear-Loop, YN-50 JAG**	**Comparison Result**
Submitter	MEDTECS (TAIWAN) CORP.	Acme Filter Mask Inc.	N/A
510(k) Number	N/A	K123115	N/A
Device Regulation number	878.4040	878.4040	same
Classification	II	II	same

Items	Subject Device ASTM Level 1/EN14683 Type IIR 3-Ply disposable Surgical Mask, Model number: FM-140G	Predicate Device Surgical Face Mask with Ear-Loop, YN-50 JAG	Comparison Result
FDA Product Code	FXX	FXX	same
Indications for Use	ASTM Level 1/EN14683 Type IIR 3-Ply disposable Surgical Mask, Model number: FM-140G are intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids and particulate material. The face masks are single use, disposable device, provided non-sterile.	Surgical Face Mask is Device that is 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 fluids and particulate material.	Identical
Prescription for use	No	No	same
Over the Counter	Yes	Yes	same
Design			
Inner and Outer Layers	Spun-bond polypropylene	Spun-bond polypropylene	same
Middle Layer	Melt blown polypropylene filter	Melt blown polypropylene filter Identical	same
Ear loops	not made with natural rubber latex	not made with natural rubber latex	same
Nose Piece	Malleable polyethylene with Galvanized iron wire	Malleable polyethylene with aluminum wire	**Different**
Dimensions	17.5cmL x 9.3cm±0.5cm H (6.89 x 3.66±0.2 inches)	17.5cm L x 9.5cm H	Identical

Items	Subject Device ASTM Level 1/EN14683 Type IIR 3-Ply disposable Surgical Mask, Model number: FM-140G	Predicate Device Surgical Face Mask with Ear-Loop, YN-50 JAG	Comparison Result
Mask Style	3 flats pleated	3 flats pleated	same
Design Features	Malleable nosepiece, flat pleated, elastic ear loops	Malleable nosepiece, flat pleated, elastic ear loops	same
Model size	One-Size (regular) fits all	One-Size (regular) fits all	Same
Sterility	Non-sterile	Non-sterile	same
Use	Single Use, Disposable	Single Use, Disposable	same
Color	Green	Green	same
Contain any drugs or biologics	No	No	same
face shield attached	no	no	same
Foam strip attached	no	no	same
LATEX-FREE	Yes	Yes	same
Performance			
ASTM F2100 Level	Level 1	Level 1	same
Fluid Resistance Performance	Fluid Resistance	Fluid Resistance	identical
Bacterial Filtration Efficiency	Higher than 99%	Higher than 99%	identical
Differential Pressure (Delta P)	Avg of 3.1 mmH_2O/cm^2	Average 3.33 (mmH_2O/cm^2)	**Different**
Particulate Filtration	Avg of 96.14% for 0.1 Sub-micron Particulate Filtration	Average 94.79% for Solid Aerosol Filtration Efficiency	**Different** *

Items	Subject Device ASTM Level 1/EN14683 Type IIR 3-Ply disposable Surgical Mask, Model number: FM-140G	Predicate Device Surgical Face Mask with Ear-Loop, YN-50 JAG	Comparison Result
Efficiency			
Flammability	Class I (No Flame Spread)	Class I (No Flame Spread)	Identical
Biocompatibility			
Cytotoxicity, ISO10993-5	Non-cytotoxic	Non-cytotoxic	Identical
Irritation, ISO10993-10	Non-irritating	Non-irritating	Identical
Sensitization, ISO10993-10	Non-sensitizing	Non-sensitizing	Identical
Labeling, Package and Storage			
Storage indication	Store in a dry and well-ventilated environment. Avoid high temperature and keep away from fire and flammable materials.	Store in a dry and well-ventilated environment. Avoid high temperature and keep away from fire and flammable materials.	Identical
Product labeling	All information showing on the Gift box	All information showing on the Gift box	Same
Package materials	Paper un-seal gift box	Paper un-seal gift box	Same
Product package	Paper Gift box (50 pcs/box) Paper Carton box (40 gift boxes/carton)	Paper Gift box (50 pcs/box) No information for Carton box	Identical
UDI included on the box	Yes (both gift box and Carton)	No information for UDI	**Different**
Shelf Life Claim	5 Years	5 Years	Same

Summary of Non-Clinical Testing

Per FDA document Guidance for Industry and FDA Staff: Surgical Masks – Premarket Notification [510(k)] Submissions, the below testing has been completed on 3 nonconsecutive lots of 32 samples for a total of 96 samples of the ASTM Level 1/EN14683 Type IIR 3-Ply disposable Surgical Mask, Model number: FM-140G ,

Item	Standard	Acceptance Criteria (for Level 1 barrier)	Results
Fluid Resistance Performance	F2100-19 clause 9.4/ASTM F1862-17: Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood	At least 29 out of 32 specimens show passing results at 80 mmHg	All samples met the predetermined acceptance criteria.
Bacterial Filtration Efficiency	F2100-19 clause 9.1/ASTM F2101-19: Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face	≥ 95%	All samples met the predetermined acceptance criteria.

Item	Standard	Acceptance Criteria (for Level 1 barrier)	Results
	Mask Materials, Using a Biological Aerosol of Staphylococcus aureus		
Differential Pressure (Delta P)	F2100-19 clause 9.2/EN14683:2019 Medical Face Masks—Requirements and Test Methods Annex C	< 5.0 mm H_2O/cm^2	All samples met the predetermined acceptance criteria.
Particulate Filtration Efficiency	F2100-19 clause 9.3/ASTM F2299-17: Test Method for Determining the Initial Efficiency of Materials Used in Medical Face Masks to Penetration by Particulates Using Latex Spheres Particulates Using Latex Spheres	≥ 95%	All samples met the predetermined acceptance criteria.
Flammability	F2100-19 clause 9.5/16 CFR 1610-2008: Standard for the Flammability of Clothing Textiles	Class I, does not Ignite	All samples met the predetermined acceptance criteria.
Cytotoxicity	ISO10993-5 Third edition: Biological evaluation of medical devices-Part 5: Tests for in vitro cytotoxicity	Non-cytotoxic	All samples met the predetermined acceptance criteria.
Irritation	ISO10993-10 Third Edition: Biological evaluation of medical devices-Part 10: Tests for irritation and skin sensitization	Non-irritating	All samples met the predetermined acceptance criteria.

Item	Standard	Acceptance Criteria (for Level 1 barrier)	Results
Sensitization	ISO10993-10 Third Edition: Biological evaluation of medical devices-Part 10: Tests for irritation and skin sensitization	Non-sensitizing	All samples met the predetermined acceptance criteria.
Performance Testing of Shipping Containers and Systems	ASTM D4169: Standard Practice for Performance Testing of Shipping Containers and Systems	No visible damage was found on sample appearance after the test (Drop, Compression, Fixed vibration, Altitude, Vibration, Concentrated Impact)	All samples met the predetermined acceptance criteria.

Conclusions:

The conclusion drawn from the non-clinical tests demonstrates that the subject device, the ASTM Level 1/EN14683 Type IIR 3-Ply disposable Surgical Mask, Model number: FM-140G, is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K123115.