September 14, 2021

Wilson Tech (International) Limited
% Julie Chen
RA Manager
Shanghai Mind-link Business Consulting Co., Ltd.
Room A08, Floor 14th, No 699, Jiaozhou Road, Jingan District
Shanghai, 200040
China

Re: K210184
Trade/Device Name: Wilson Tech Disposable Medical Face Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: September 02, 2021
Received: September 07, 2021

Dear Julie Chen:

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 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

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)*
K210184

Device Name
Wilson Tech Disposable Medical Face Mask

Indications for Use *(Describe)*

Wilson Tech Disposable Medical 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. Wilson Tech Disposable Medical 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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510k Summary - K210184

I. SUBMITTER:

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Summary prepared: September 14, 2021

II. DEVICE

Name of Device: Wilson Tech Disposable Medical Face Mask
Regulation Number: 21 CFR PART 878.4040
Common Name: Surgical Mask
Classification Name: Surgical Mask
Regulatory Class: II
Product Code: FXX

III. PREDICATE DEVICE

Primary predicate device: DemeMASK Surgical Mask (K201479)

IV. DEVICE DESCRIPTION

Wilson Tech Disposable Medical Face Mask is composed of three layers and is flat-pleated. The mask materials consist of an outer layer (spun-bond polypropylene), a middle layer, between the outer layer and inner layers (melt-blown polypropylene), and an inner layer (spun-bond polypropylene). Each mask contains ear loops to secure the mask over the users' mouth and face and includes a malleable nose piece made of galvanized iron wire coated with polyethylene to provide a firm fit over the nose.

V. AVAILABLE MODELS

Wilson Tech Disposable Medical Face Mask contains only one model which is a blue mask, barrier protection level 3, size 175mm*95mm and ear loop type.

VI. INDICATIONS FOR USE

Wilson Tech Disposable Medical 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. Wilson Tech Disposable Medical Face Mask is a single use, disposable device, provided non-sterile.

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Wilson Tech Disposable Medical Face Masks are compared with the predicate device (DemeMASK Surgical Mask(K201479)). The results are shown below in the Technological Characteristics Comparison Table:

DEVICE	**Subject Device Wilson Tech Disposable Medical Face Mask**	**Primary Predicate Device DemeMASK Surgical Mask (K201479)**	**Comparison**
Intended Use	Wilson Tech Disposable Medical Face Mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. Wilson Tech Disposable Medical Face Mask is intended for use in infection control practices to reduce the potential exposure to blood and body fluids. Wilson Tech Disposable Medical Face Mask is 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
Classification Product Code	FXX	FXX	Same
Ear Loop Model	Ear Loops	Ear Loops	Same
Materials			
Outer Facing Layer	25gsm SS (spunbond – spunbond) Nonwoven fabric	Spunbond polypropylene	Similar
Middle Layer	25gsm meltblown Nonwoven fabric	Meltblown polypropylene filter	Similar
Inner Facing Layer	25gsm SS (spunbond – spunbond) Nonwoven fabric	Spunbond polypropylene	Similar
Nose Piece	Galvanized iron wire coated with polyethylene	Galvanized wire coated with polyethylene	Similar

Ear Loops	11% Spandex, 13% Polyester, 76% Nylon	Spandex and Nylon – Not made from natural rubber latex	Similar
Design Features			
Style	Flat - Pleated	Flat - Pleated	Same
Multiple Layers	3 Layers	3 Layers	Same
Single Use	Single use	Single use	Same
Sterility			
Sterile	Non-sterile	Non-sterile	Same
Dimension			
Length Width	Length:175mm±5mm Width:95mm±5mm	Length:17.5cm±1cm Width: 9.5 cm±1 cm	Same
Technological Characteristics Product Barrier Specifications Per ASTM F2100 – Meets Level 3			
Fluid Resistance ASTM F1862	Pass at 160mmHg	Pass at 160 mmHg (Level 3 Fluid Resistance)	Same
Particulate Filtration Efficiency (PFE) ASTM F2299	Pass at >98%	Pass at ≥99%	Same
Bacterial Filtration Efficiency (BFE) ASTM F2101	Pass at >98%	Pass at ≥99%	Same
Differential Pressure (Delta P) MIL-M-36954C	Pass at ＜6 mmH2O/cm^2	Average 3.6 mmH2O/cm^2	Same
Flammability 16CFRPART 1610	Class 1 Non-Flammable	Class 1 Non-Flammable	Same
Biocompatibility			
Cytotoxicity	Non-cytotoxic	Non-cytotoxic	Same
Irritation	Non-irritating	Non-irritating	Same
Sensitization	Non-sensitizing	Non-sensitizing	Same

VIII. PERFORMANCE DATA

Non-Clinical Performance Test Conclusion

Non-clinical tests were conducted to verify that the proposed device met all design specifications was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the Disposable Surgical Masks complies with the following standards:

- ASTM F2100-19 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
- MIL-M- 36954C Military Specification, Mask, Surgical, Disposable
- 16 CFR Part 1610 Standard for the Flammability of Clothing
- ISO10993-1 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- ISO10993-5 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity of medical devices
- ISO10993-10 Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization

Non-clinical Testing Summary:

Test Methodology	Purpose of the test	Acceptance criteria	Test Results
Bacterial Filtration Effciency	The test was performed in accordance with ASTM F2101: 2019 Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus to determine the bacterial filtration efficiency(BFE) of the test article	Level 3: ⩾98%	32/32 Passed at ⩾99.3%
Particulate Filtration Efficiency	The test was performed in accordance with ASTM F2299 Standard Test Method for Determining the Initial Efficiency of Material Used in medical Face Masks to Penetration by Particulates using Latex Spheres to determine the particle filtration efficiency (PFE) of the test article	Level 3: ≥98%	32/32 Passed at ⩾99.28%
Differentail Pressure (delta-P)	The test was performed in accordance with MIL-M- 36954C Military Specification, Mask, Surgical, Disposable	<6.0 mmH2O/cm^2	32/32 Passed at <4.9 mmH2O/cm^2

Resistance to penetration by synthetic blood, minimum pressure in mm Hg for pass result	The test was performed in accordance with ASTM F1862/F1862M Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (HorizontalProjection of Fixed Volume at a Known Velocity) to evaluate the effectiveness of the test sample from possible exposure to blood and other body fluids.	Level 3: No penetration at 160 mmHg	32/32 Passed at160mmHg
Flammability	Level 3: No penetration at 160 mmHg	Class 1	32/32 Passed Class 1 requirement

Biocompatibility Testing Summary:

Test Methodology	Purpose of the test	Acceptance criteria	Test Results
In vitro Cytotoxicity test	The purpose of the biocompatibility testing is to demonstrate the biocompatibility of the subject device.	Non-Cytotoxic	Pass Under the conditions of the study, the device is non-cytotoxic
Skin sensitization Test		Non-Sensitizing	Pass Under the conditions of the study, the device is non-sensitizing
Skin Irritation Test		Non-Irritating	Pass Under the conditions of the study, the device is non-irritating

Clinical Test Conclusion

No clinical study is included in this submission.

IX. CONCLUSION

The conclusion drawn from the nonclinical tests demonstrates that the subject device, Wilson Tech Disposable Medical Face Mask is as safe, as effective, and performs as well as or better than the legally marketed predicate device DemeMASK Surgical Mask(K201479).