November 23, 2021

AOK Tooling Limited
% Paul Dryden
Consultant
AOK Tooling Limited % ProMedic, LLC
131 Bay Point Dr. NE
St. Petersburg, Florida 33704

Re: K211956
Trade/Device Name: 039 Medical Surgical Face Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: October 19, 2021
Received: October 22, 2021

Dear Paul Dryden:

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, 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)*

K211956

Device Name

039 Medical Surgical Face Mask

Indications for Use *(Describe)*

The 039 Medical 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 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) XX 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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510(k) Summary

Date Prepared: 21-Nov-2021

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Tel - +852-0-23101703

Sponsor Contact: Francis Nithyananthan
Project Director

Submission Correspondent: Paul Dryden
ProMedic Consulting LLC

Proprietary or Trade Name: 039 Medical Surgical Face Mask

Common/Usual Name: Mask, Surgical

Classification Name: Product Code – FXX – Mask, Surgical

Predicate Devices: Jiangsu Medplus Non-woven Manufacturer Co., Ltd. - K202605

Device Description: The 039 Medical Surgical Face Mask is single use, four-layer folded masks with ear loops, or straps to tie behind the user's head, and a nose piece. The ear loops are held in place over the users' 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 in the layers of facemask is to allow the user to fit the facemask around their nose, which is made of malleable polyethylene wire. The surgical face masks will be provided in blue. The 039 Surgical Face Mask is sold non-sterile and are intended to be single use, disposable devices.

Principle of Operation: A surgical mask covers the user's nose and mouth and provides a physical barrier to fluids and particulate materials.

Indications for Use: The 039 Medical Surgical Face Mask 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.

Description	Predicate Device	Proposed Device	Comparison
Manufacturer	Jiangsu Medplus Non-woven Manufacturer Co., Ltd.	AOK Tooling Ltd.	
510(k) Number	K202605	K211956	
Model Name	Standard Procedure Mask, Standard Surgical Mask	039 Medical Surgical Face Mask	
Classification	Class II Device FXX 21 CFR878.4040	Class II Device FXX 21 CFR878.4040	Identical
Intended use / Indications for Use	The device 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. This is a single use, disposable device, provided non-sterile.	The 039 Medical Surgical Face Mask 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.	Identical
Mask Style	Flat pleated	Folded	The mask style is different, but performance is similar to the predicate*
Materials			
Cover Fabric(s)	Spunbonded nonwoven and Melt blown nonwoven fabric	Non-woven polypropylene; Melt blown non-woven polypropylene filter	The difference does not impact device performance*
Nose Piece	Plastic	Silicone	The difference does not impact device performance*
Ear Loops / Tie-on	Polyester and spandex and Spunbonded nonwoven	Spandex	Identical
Color	Blue	Blue and White	Similar
Design	Ear loop and tie-on	Ear loop and tie-on	Identical
Dimension (Width / Length) Flat even though subject device is folded	175×95 mm	Small – 208x111 mm Medium – 226x124 mm Large – 250x138 mm Xlarge – 262x144 mm	The size difference does not impact device performance*
OTC Use	Yes	Yes	Identical
Use	Single Use, Disposable	Single Use, Disposable	Identical

ASTM 2100 Level	Level 2	Level 2	Identical
Fluid resistance	Pass at 120mmHg	Pass at 120mmHg	Identical
Particulate efficiency level	≥98%	≥98%	Identical
Bacterial filtration level	≥98%	≥98%	Identical
Differential pressure	＜6.0 mm H2O/cm2	＜6.0 mm H2O/cm2	Identical
Flammability	Class I	Class I	Identical
Biocompatibility Tested	Cytotoxicity Sensitization Irritation	Cytotoxicity Sensitization Irritation	Identical
Sterility	Non-sterile	Non-sterile	Identical

Indications for Use –
The indications for use are identical for the proposed device when compared to the predicate –
Discussion – Each device is indicated to cover a user's nose and mouth and provides a physical barrier to fluids and particulate materials.

Technology and construction –
The design, fabrication, shape, size, etc. are equivalent to the predicate - Jiangsu Medplus Non-woven Manufacturer Co., Ltd. - K202605.
Discussion – This mask is not a flat-pleated style and covers a larger surface area of the user's face. However, the difference in mask style of flat pleated vs. folded should not impact the substantial equivalence of the subject device to the predicate. Our testing demonstrated that the subject device has similar performance to the predicate.

Environment of Use –
The environments of use are identical to predicate - Jiangsu Medplus Non-woven Manufacturer Co., Ltd. - K202605.
Discussion – The environments of use are the same.

Patient Population –
The patient population of the proposed device and predicate - Jiangsu Medplus Non-woven Manufacturer Co., Ltd. - K202605.
Discussion – The identified patient population is equivalent to the predicate.

Non-Clinical Testing Summary –
Performance testing was performed following ASTM F2100-2019 Standard Specification for Performance of Materials Used in Medical Face Masks with reference to Guidance for Industry and FDA Staff: Surgical Masks – Premarket Notification [510k] Submission (2004). Three separate non-consecutive lots of 32 samples each were tested.

Test Methodology	Purpose	Acceptance Criteria for Level 2 Barrier	Results
Section 6.1 Bacterial Filtration Efficiency ASTM F2101	Measure bacterial filtration efficiency	>98% 87 of 96 pass	99.9% 96 of 96 passed
Section 6.1 Differential Pressure (mm H_2O/cm^2) EN14683:2019+AC:2019 Annex C	Determine breathability of a mask	<6.0 87 of 96 pass	Average <3.8 96 of 96 passed
Section 6.1 Sub-micron Particulate Filtration Efficiency ASTM F2299/F2299M-03	Measure initial particle filtration efficiency	≥ 98% 87 of 96 pass	>99% 96 of 96 passed
Section 6.1 Resistance to Penetration by Synthetic Blood ASTM F1862/F 1862M-2017	Evaluate the resistance to penetration by impact of small volume of synthetic blood	120 mmHg Visual inspection 87 of 96 pass	None seen in 91 of 96 samples
Section 6.2 Flame spread 16CFR Part 1610-2008	Response of materials to heat and flame	Class 1 87 of 96	96 of 96 passed

Bench testing –
We performed the following tests: Fluid Resistance, Flammability, Particulate Filtration Efficiency**,** Bacterial Filtration Efficiency, Differential Pressure.
Discussion – The results were similar.

Biocompatibility –
Both devices are considered Surface Contact, Intact Skin, Limited Duration of Use.
Discussion – The proposed device materials were found to meet the applicable requirements for biocompatibility safety for the intended population.

Conclusion:
The conclusions drawn from the nonclinical tests demonstrate that the 039 Medical Surgical Face Mask device is as safe, as effective, and performs as well as or better than the legally marketed device in K202605.