September 4, 2020

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

Re: K201517
Trade/Device Name: Plain Surgical Face Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: June 4, 2020
Received: June 8, 2020

Dear Mr. 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,

CAPT Elizabeth Claverie, MS
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)*
K201517

Device Name
Plain Surgical Face Mask

Indications for Use *(Describe)*
The Plain 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. The face mask is 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.

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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510(k) Summary

Date Prepared: 02-Sep-2020

Sponsor:
AOK Tooling Limited
#8, Longtian 3Rd, Longtian Street, Pingshan Dist.
Shenzhen, China 518122
Tel: +852-0-23101703

Sponsor Contact: Francis Nithyananthan
Project Director

Proprietary or Trade Name: Plain Surgical Face Mask

Common Name: Mask, Surgical

Classification Name: Surgical apparel
Classification: Class II
Product Code: FXX
Regulation Number: 21 CFR 878.4040

Predicate Devices: Wuhan Dymex Healthcare Co., Ltd. - Surgical Face Mask - K182515

Device Description:
The Plain Surgical Face Mask is a single use, three-layer, flat–folded masks with ear loops and adjustable clips and nose piece. The Plain Surgical Face Mask is manufactured with three layers, the inner and outer layers are made of spunbonded polypropylene, and the middle layer is made of melt blown polypropylene filter. The ear loops are held in place over the users' mouth and nose by two elastic ear loops welded to the facemask and with adjustable clips. 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 are sold non-sterile and are intended to be single use, disposable devices.

Indications for Use:
The Plain 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. The face mask is 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.

510(k) Summary

Summary of Technological Characteristics:

Table 1: Comparison to Predicate

Description	Predicate Device	Proposed Device	Comparison
Manufacturer	Wuhan Dymex Healthcare Co Ltd	AOK Tooling Ltd.	
510(k) Number	K182515	K201517	
Device Name	Surgical Face Mask	Plain Surgical Face Mask	
Classification	Class II Device FXX 21 CFR878.4040	Class II Device FXX 21 CFR878.4040	Same
Intended use	The 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. The face mask is 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 Plain 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. The face mask is 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
Model	Ear Loops, Flat Pleated 3 layers	Ear Loops with adjustable clips, Flat Pleated, 3 layers	Similar
Materials			
Outer Cover Fabrics	Spun-bond polypropylene	Spun-bond polypropylene	Same
Middle Layer	Melt blown polypropylene filter	Melt blown polypropylene filter	Same
Inner Facing	Spun-bond polypropylene	Spun-bond polypropylene	Same
Nose Piece	Malleable polyethylene wire	Malleable polyethylene wire	Same
Ear Loops/Adjustable Clips	Spandex ear loops	Spandex ear loops and polypropylene clips	Similar
Color	Yellow	White	Different
Dimension (Length)	17.5cm ± 0.2cm	17.5cm ± 0.2cm	Same
Dimension (Width)	9.5cm ± 0.2cm	9.5cm ± 0.2cm	Same
OTC Use	Yes	Yes	Same
Sterile	Non-sterile	Non-sterile	Same
Use	Single Use, Disposable	Single Use, Disposable	Same
ASTM 2100 Level	Level 2	Level 2	Same

Non-Clinical Testing Summary:

The proposed device was tested and conformed to the following standards and the requirements stated in the Guidance for Industry and FDA Staff: *Surgical Masks – Premarket Notification [510(k)] Submission* issued on March 5, 2004.

Table 2: Performance Testing

Description	Subject Device	Acceptance Criteria
Fluid Resistance (ASTM F1862)	29 out of 32 pass at 120 mmHg	29 out of 32 pass at 120 mmHg
Flammability class 16 CFR Part 1610	Class I Non-Flammable	Meets Class I, No flame spread on 5 of 5
Particulate Filtration Efficiency ASTM F2299	Average 99.79% Efficiency	≥ 98% Efficiency
Bacterial Filtration Efficiency ASTM F2101	>99% Efficiency	≥ 98% Efficiency
Differential Pressure (Delta P) ASTM F2100-9 and EN 14683:2019	Average 3.2 mmH_2O/cm^2 (Range 3.1-3.4)	< 5.0 mmH_2O/cm^2

510(k) Summary

All the testing samples met the performance acceptance criteria.

Table 3: Biocompatibility Testing

Item	Proposed device	Result
Cytotoxicity	Under the conditions of the study, the device meets ISO 10993-5 requirements.	Pass
Irritation	Under the conditions of the study, the device meets ISO 10993-10 requirements.	Pass
Sensitization	Under the conditions of the study, the device meets ISO 10993-10 requirements.	Pass

Conclusion:
The conclusion drawn from the nonclinical tests demonstrate that the subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate K182515, Wuhan Dymex Healthcare Surgical Face Mask.