July 27, 2022

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

Re: K220876
Trade/Device Name: AOK 95A Medical Mask (20200049)
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: July 20, 2022
Received: July 22, 2022

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
Brent Showalter, Ph.D.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic 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)*

K220876

Device Name

AOK 95A Medical Mask (20200049)

Indications for Use *(Describe)*

The AOK 95A Medical Mask (20200049) 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: 20-Jul-2022

AOK Tooling Limited
Flat 2009, 20/F, Kowloon Plaza, No.485
Castle Peak Road, Cheung Sha Wan, Kowloon
Hong Kong, China

Official Contact: Jerry Teng
1-626-203-3809

Proprietary or Trade Name: AOK 95A Medical Mask (20200049)
Common/Usual Name: Mask, Surgical
Classification Name: Product Code – FXX – Mask, Surgical

Predicate Device: AOK Tooling Limited - K211956
Common/Usual Name: Mask, Surgical
Classification Name: Product Code – FXX – Mask, Surgical

Device Description: The AOK 95A Medical Mask (20200049) 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 AOK 95A Medical Mask will be provided in white and blue. The AOK 95A Medical Mask is sold non-sterile and are intended to be single use, disposable devices.

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

Indications for Use: The AOK 95A Medical Mask (20200049) 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.

510(k) Summary

Description	Subject Device	Predicate Device	Differences
Manufacturer	AOK Tooling Ltd.	AOK Tooling Ltd.	
510(k) Number	TBD	K211956	
Model Name	AOK 95A Medical Mask (20200049)	039 Surgical Face Mask	
Classification	Class II Device FXX 21 CFR 878.4040	Class II Device FXX 21 CFR 878.4040	Identical
Intended use	The AOK 95A Medical Mask (20200049) 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.	The 039 Surgical Face 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.	Identical
Mask Style	Flat pleated	Folded	The mask style is different, but performance is similar to the predicate
Materials			
Cover Fabric(s)	Non-woven polypropylene; Melt blown non-woven polypropylene filter	Non-woven polypropylene; Melt blown non-woven polypropylene filter	Identical
Outer Cover Fabrics	50g Non-woven Fabric	50g Non-woven Fabric	Identical
Middle Layer-1	20g Melt blown Non-woven	20g Melt blown Non-woven	Identical
Middle Layer-2	70g PET Non-woven Fabric	70g PET Non-woven Fabric	Identical
Inner Facing	30g Non-woven Fabric	30g Non-woven Fabric	Identical
Nose Piece	Plastic	Silicone	The difference does not impact device performance
Ear Loops / Tie-on	Spandex	Spandex	Identical
Color	Blue and White	Blue and White	Similar
Design	Ear loop and tie-on	Ear loop and tie-on	Identical
Dimension (Width / Length)	Small – 165mm × 70mm Medium – 190mm × 80mm Large – 210mm × 86mm	Small – 208x111 mm Medium – 226x124 mm Large – 250x138 mm XL – 262x144 mm	The size difference and lack of a small size mask does not impact device performance or safety

510(k) Summary

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	Cytotoxicity Sensitization Irritation	Cytotoxicity Sensitization Irritation	Identical
Sterility	Non-sterile	Non-sterile	Identical

510(k) Summary

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 - AOK Tooling Ltd. - 039 Surgical Face Mask - K211956.
Discussion – This mask is a flat pleated style and covers a smaller surface area of the user's face. However, the difference in mask style of pleated vs. folded does not impact the substantial equivalence of the subject device to the predicate. There is no specific language within FDA product code FXX or its guidance document on the technological characteristics for a surgical mask that would relate to and/or limit the design to a flat pleated style (subject device) vs. vertical folded style. Thus, the difference in design of a pleated vs. folded mask does not impact the substantial equivalence of the subject device to the predicate. Our performance testing demonstrated that the subject device has similar performance to the predicate.

Environment of Use –
The environments of use are identical to predicate - AOK Tooling Ltd. -039 Surgical Face Mask - K211956.
Discussion – The environments of use are the same.

Patient Population –
The patient population of the proposed device and predicate - AOK Tooling Ltd. - 039 Surgical Face Mask - K211956.
Discussion – The identified patient population is equivalent to the predicate.

Non-Clinical Testing Summary –

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.

Discussion of Differences –

There are no significant differences between the subject and predicate device, both of which are made by the same manufacturer for AOK Tooling. The main differences are the mask style (flat-pleated vs. folded) and the size of the mask. Testing demonstrated that we are equivalent to the predicate device despite a difference in mask size and style.

Substantial Equivalence Conclusion

The sponsor has demonstrated through performance testing, design and features, and non-clinical testing that the subject device and predicate have been found to be substantially equivalent.