January 13, 2021

Han Zhaoqing Sporting Goods Company Limited
% Cassie Lee
Manager
Share Info (Guangzhou) Medical Consultant Ltd.
No. 1919-1920, Building D3, Minjie Plaza, Shuixi Road,
Huangpu District
Guangzhou, Guangdong 510700
China

Re: K202314
Trade/Device Name: Procedure face mask (Model: KKF-2A)
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: August 11, 2020
Received: August 17, 2020

Dear Cassie Lee:

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 and Part 809); 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 CAPT Elizabeth Claverie, M.S.
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)*
K202314

Device Name
Procedure face mask (Model: KKF-2A)

Indications for Use *(Describe)*
The Procedure 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(s), 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

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92.

Subject Device: Procedure face mask (Model: KKF-2A)
510(k) Number: K202314

1. Date of the summary prepared: December 30, 2020

2. Submitter's Information

510(k) Owner's Name: Han Zhaoqing Sporting Goods Company Limited
Establishment Registration Number: 3016690756
Address: NO.2-1, Kang tai Street, High-tech zone, Zhaoqing City, Guangdong Province, P.R.China
Contact Person: Zhang Ming
Email: info@koumask.co

Application Correspondent:
Contact Person: Ms. Cassie Lee
Share Info (Guangzhou) Medical Consultant Ltd.
Address: No. 1919-1920, Building D3, Minjie Plaza, Shuixi Road, Huangpu District, Guangzhou, China
Tel: +86 20 8266 2446
Email: regulatory@glomed-info.com

3. Subject Device Information

Type of 510(k): Traditional
Classification Name: Mask, Surgical
Common Name: Surgical Face Mask
Trade Name: Procedure face mask
Model Name: KKF-2A
Review Panel: General Hospital
Product Code: FXX
Regulation Number: 878.4040
Regulatory Class: II

4. Predicate Device Information

Sponsor: Wuhan Dymex Healthcare Co., Ltd
Trade Name: Surgical Face Mask
Classification Name: Mask, Surgical
510(K) Number: K182515
Review Panel: General Hospital
Product Code: FXX
Regulation Number: 878.4040
Regulatory Class: II

5. Indications for Use

The Procedure 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(s), provided non-sterile.

6. Device Description

The Procedure face mask is a three-layer, flat-pleated style mask with ear loops and nose piece design for fitting the face mask around the nose and mouth. The proposed device is manufactured with three layers, the inner (Layer #3) and outer (Layer #1) layers are made of spun-bond polypropylene, and the middle layer (Filter layer) is made of melt-blown polypropylene. The ear loops are made of Polyester & elastane, and the nose piece is made of Malleable polyethylene wire. The ear loops are held in place over the users' mouth and nose by two elastic ear loops welded to the face mask. 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 face masks will be provided in blue. The face masks are sold non-sterile and are intended to be single-use, disposable devices.

7. Summary of Technological Characteristics

The differences between the subject device and predicate devices do not raise new issues of safety or effectiveness.

Elements of Comparison		**Subject Device**	**Predicate Device**	**Result**
Company		Han Zhaoqing Sporting Goods Company Limited	Wuhan Dymex Healthcare Co., Ltd	--
510 (k) Number		K202314	K182515	--
Trade Name		Procedure face mask	Surgical Face Mask	--
Classification Name		Mask, Surgical	Mask, Surgical	Same
Classification		Class II Device, FXX (21 CFR 878.4040)	Class II Device, FXX (21 CFR 878.4040)	Same
Indication for use		The Procedure 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(s), 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(s), provided non-sterile.	Same
Model		KKF-2A (Ear Loops, Flat Pleated, 3 Layers)	Ear Loops, Flat Pleated, 3 layers	Same
Material	Outer facing layer	Spun-bond polypropylene	Spun-bond polypropylene	Same
	Middle layer	Melt blown polypropylene filter	Melt blown polypropylene filter	Same

Elements of Comparison		Subject Device	Predicate Device	Result
	Inner facing layer	Spun-bond polypropylene	Spun-bond polypropylene	Same
	Nose piece	Malleable polyethylene wire	Malleable polyethylene wire	Same
	Ear loops	Polyester & elastane	Spandex	Similar Note 1
Color		Blue	Yellow	Similar Note 1
Dimensions		Length: 17.5 cm ± 2 cm Width: 9.5 cm ± 2 cm Length of Nose piece: 10cm Length of Ear loop (for single side): 20cm	Length: 17.5 cm ± 0.2 cm Width: 9.0 cm ± 0.2 cm	Similar Note 1
OTC use		Yes	Yes	Same
Sterility		Non-Sterile	Non-Sterile	Same
Use		Single Use, Disposable	Single Use, Disposable	Same
ASTM F2100 Level		Level 2	Level 2	Same
Fluid Resistance Performance		Passed at 120mm Hg	32 out of 32 pass at 120 mm Hg	Same
Particulate Filtration Efficiency		Passed at 99.8%	99.7%	Similar Note 2
Bacterial Filtration Efficiency		Passed at 99.8%	99.9%	Similar Note 2
Differential Pressure		Passed at 3.8 mmH_2O/cm^2	4 mmH_2O/cm^2	Similar Note 1
Flammability		Class 1	Class 1	Same
Biocompatibility	Cytotoxicity	Under the conditions of the study, the subject device extract was determined to be non-cytotoxic.	Under the conditions of the study, the device is noncytotoxic.	Same
	Irritation	Under the conditions of the study, the subject device non-polar and polar extracts were determined to be non-irritating.	Under the conditions of the study, the device is nonirritating.	Same
	Sensitization	Under the conditions of the study, the subject device non-polar and polar extracts were determined to be non-sensitizing.	Under the conditions of the study, the device is nonsensitizing.	Same

Comparison in Detail(s):

Note 1:

Although the "Ear loops", "Size and Dimensions" and "Color" of subject device is a little different from the predicate device, and they all meet the requirements of essential performance standard ASTM F2100 and ISO 10993 series. So, the differences between the predicate device and subject device will not affect the safety and effectiveness of the subject device.

Note 2:

Although the "Particulate Filtration Efficiency", "Bacterial Filtration Efficiency" and "Differential Pressure" of subject device is a little different from the predicate device, and they all meet the requirements of essential

performance standard ASTM F2100. So, the differences between the predicate device and subject device will not affect the safety and effectiveness of the subject device.

8. Summary of Non-Clinical Performance Testing
Performance Testing summary:

Item	Proposed device	Acceptance Criteria for Level 2	Test Results
Fluid Resistance Performance (mmHg) ASTM F1862	Passed at 120mm Hg	29 out of 32 pass at 120 mmHg	PASS
Particulate Filtration Efficiency Performance (%) ASTM F2299	Passed at 99.8%	≥ 98%	PASS
Bacterial Filtration Efficiency Performance (%) ASTM F2101	Passed at 99.8%	≥ 98%	PASS
Differential Pressure (Delta-P) (mm H2O/cm^2) MIL-M-36954C	Passed at 3.8 mmH_2O/cm^2	<6.0 mm H_2O/cm^2	PASS
Flammability class Class 1 16 CFR 1610	Class 1	Class 1	PASS

Biocompatibility Testing Summary:
According to ISO 10993-1: 2018, the nature of body contact for the subject device is the Surface Device category, Skin Contact, and duration of the contact is A-Limited (＜24 h). The following tests for the subject device were conducted to demonstrate that the subject device is biocompatible and safe for its intended use:

Test Item	Proposed device	Result
Cytotoxicity	Under the conditions of the study, the subject device extract was determined to be non-cytotoxic.	PASS
Irritation	Under the conditions of the study, the subject device non-polar and polar extracts were determined to be non-irritating.	PASS
Sensitization	Under the conditions of the study, the subject device non-polar and polar extracts were determined to be non-sensitizing.	PASS

9. Summary of Clinical Performance Test

No clinical study is included in this submission.

10. Final Conclusion

The subject device is as safe, as effective, and perform as well or better than the legally marketed predicated K182515, Surgical face Mask.