June 16, 2021

Guangdong Haiou Medical Apparatus Co., Ltd.
% Salon Chen
System Engineer
IMD Medical & Drug technology service institutions
Tianbao office room 225,Sha Tai Road No.209
ShenZhen city, Guangdong Province 518117
China

Re: K203200
Trade/Device Name: Disposable Medical Surgical Face Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: May 13, 2021
Received: May 13, 2021

Dear Salon 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,

Clarence W. Murray, III, Ph.D.
Acting 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)*
K203200

Device Name
Disposable Medical Surgical Face Mask

Indications for Use *(Describe)*
Disposable Medical Surgical Face Mask is indicated as a protective nose and mouth covering for healthcare workers and patients involved in medical and surgical procedures. The masks are indicated in any procedure or situation where there is a risk of exposure to microorganisms and body fluids.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

1. Submitter's Information

- Company Name: Guangdong Haiou Medical Apparatus Co., Ltd.
- Establishment Registration Number: 3010596027
- Address:Nanyuan Industrial Zone, North Liusha, Puning City, Guangdong, China
- Phone:+86-663-2758666
- Fax: +86-663-2905999
- Contact Person(Title):Zhang Zhuo Xuan(General Manager)
- E-mail: hoyl@haiou.net.cn

2. Device Information

- Trade Name: Disposable Medical Surgical Face Mask
- Common Name: Mask,Surgical
- Classification Name: Surgical Apparel
- Model: HO-KZ01
- 510(k) Number: K203200

3. Classification

- Classification Product Code: FXX
- Regulation Number: 21 CFR 878.4040
- Classification: Class II
- Review Panel: General Hospital

4. Predicate Device Information:

- 510(k) Number: K201137
- Predicate Device Name: ASEPT® Surgical Face Mask
- Manufacturer: PFM Medical, Inc.
- This predicate has not been subject to a design-related recall
- No reference devices were used in this submission.

5. Application Correspondent

- Company Name: IMD Medical & Drug technology service institutions
- Phone: +86-18613190779
- Fax: +86-755-62809168
- Contact Person(Title): Salon Chen (System engineer)
- E-mail: 33999439@qq.com

6. Device Description

Disposable Medical Surgical Face Mask is a single-use, three layer, flat-folded mask with ear loops and nose piece. The inner and outer layers are constructed of spun-bond polypropylene and the middle layer is constructed of melt blown polypropylene filter. The mask is held in place over the mouth and nose by two elastic loops welded to the facemask. The elastic loops are not made with natural rubber latex. The nose piece is made of malleable polyethylene with aluminum wire and allows the user to fit the facemask around their nose. Disposable Medical Surgical Face Mask is sold non-sterile and is intended to be a single use, disposable device.

7. Indications for Use Statement

Disposable Medical Surgical Face Mask is indicated as a protective nose and mouth covering for healthcare workers and patients involved in medical and surgical procedures. The masks are indicated in any procedure or situation where there is a risk of exposure to microorganisms and body fluids.

8. Comparison to the Predicate Device

Elements of Comparison	Proposed Device	Predicate Device	Judgment
Company Name	Guangdong Haiou Medical Apparatus Co., Ltd..	PFM Medical, Inc.	/
Device Name	Disposable Medical Surgical Face Mask	ASEPT® Surgical Face Mask	/
510(k) Number	K203200	K201137	/
Classification Product Code	FXX	FXX	Same
Regulation	21 CFR 878.4040	21 CFR 878.4040	Same
Classification Name	Surgical Apparel	Surgical Apparel	Same
Class	2	2	Same
Prescription or OTC	OTC	OTC	Same
Intended Use & Indications for Use	Disposable Medical Surgical Face Mask is indicated as a protective nose and mouth covering for healthcare workers and patients involved in medical and surgical procedures. The masks are indicated in any procedure or situation where there is a risk of exposure to microorganisms and body fluids.	The ASEPT® Surgical Face Mask is indicated as a protective nose and mouth covering for healthcare workers and patients involved in medical and surgical procedures. The masks are indicated in any procedure or situation where there is a risk of exposure to microorganisms and body fluids.	Same

Materials	**Inner and Outer Layers**	Spun-bond polypropylene	Spun-bond polypropylene	Same
	Middle Layer	Melt blown polypropylene filter	Melt blown polypropylene filter	
	Ear Loops	Polyester	Polyester	
	Nose Piece	Malleable polyethylene with aluminum wire	Malleable polyethylene with aluminum wire	
Dimension		17.5cm length x 9.5cm height	17.5cm length x 9.5cm height	Same
Mask Style		Pleated	Pleated	Same
Design Features		Malleable nosepiece, flat pleated, elastic ear loops	Malleable nosepiece, flat pleated, elastic ear loops	Same
Sterility		Non-sterile	Non-sterile	Same
Use		Single Use,Disposable	Single Use,Disposable	Same
Color		Blue and White	Blue and White	Same
ASTM F2100 level		Level 3	Level 2	Different 1
Resistance to Penetration by Synthetic Blood		Level 3: 160 mm Hg	Level 2: 120 mm Hg	
Differential Pressure		Level 3: < 6.0	Level 2: <6.0	Same
Flammability		Class 1	Class 1	Same
Bacterial Filtration Efficiency (BFE)		Level 3: ≥ 98	Level 2: ≥ 98	Same
Sub-Micron Particulate Filtration		Level 3: ≥ 98	Level 2: ≥ 98	Same

Biocompatibility	**Cytotoxicity,ISO 10993-5:2009**	Non-cytotoxic	Non-cytotoxic	Same
	Irritation,ISO 10993-10:2002	Non-irritating	Non-irritating	
	Sensitization,ISO 10993010:2002	Non-sensitizing	Non-sensitizing	

Analysis:

Different 1:According to ASTM F2100 standard and test result, Haiou's Disposable Medical Surgical Face Mask ratings is level 3, the level 3 performance is the better than the level 2 performance in ASTM F2100 standard,thus,Haiou's Disposable Medical Surgical Face Mask is safe.

9. Non-Clinical Test Conclusion

Non-clinical data:

Per FDA document Guidance for Industry and FDA Staff: Surgical Masks – Premarket Notification [510(k)] Submissions, the below testing has been completed on the subject device:

Item	Standard	Acceptance Criteria	Results
Fluid Resistance Performance	ASTM F1862: Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood	Level 3:160 mm Hg	All samples met the predetermined acceptance criteria.
Bacterial Filtration Efficiency	ASTM F2100-19: Standard Specification for Performance of Materials Used in Medical Face Masks	⩾ 98%	All samples met the predetermined acceptance criteria.
Differential Pressure	ASTM F2100-19:	< 6.0 mm H_2O/cm^2	All samples met the

(Delta P)	Standard Specification for Performance of Materials Used in Medical Face Masks		predetermined acceptance criteria.
Particulate Filtration Efficiency	ASTM F2100-19: Standard Specification for Performance of Materials Used in Medical Face Masks	⩾ 98%	All samples met the predetermined acceptance criteria.
Flammability	21 CFR 1610	Class I, Does not Ignite	All samples met the predetermined acceptance criteria.
Cytotoxicity	ISO 10993-5: Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity	Non-cytotoxic	All samples met the predetermined acceptance criteria.
Irritation	ISO 10993-10: Biological evaluation of medical devices — Part 10: Tests for	Non-irritating	All samples met the predetermined acceptance criteria.

	irritation and skin sensitization		
Sensitization	ISO 10993-10: Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization	Non-sensitizing	All samples met the predetermined acceptance criteria.

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10. Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(k) Disposable Medical Surgical Face Mask is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K201137.