December 11, 2023

Shenzhen Hygenix Industrial Co., Ltd
% Jerry Doane
US Agent
FDAbasics
5815 SW 11th Court Rd
Ocala, Florida 34473

Re: K232797
Trade/Device Name: Hygenix
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: August 21, 2023
Received: September 12, 2023

Dear Jerry Doane:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Allan Guan -S

For Bifeng Qian, M.D., Ph.D.
Assistant Director

DHT4B: Division of Infection Control
and Plastic and Reconstructive 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)*
K232797

Device Name
Hygenix

Indications for Use *(Describe)*
The Hygenix is intended to be worn to protect both the patient and health care 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 device is disposable, non-sterile and for single use only.

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 (K232797)

[AS REQUIRED BY 21CFR807.92]

I. APPLICANT INFORMATION

Submitter's Name	Shenzhen Hygenix Industrial Co., Ltd
Submitter's Address	3rd Floor, Building A3, Fang Xing Technology Park, Longgang District, Shenzhen, China, 518100
Name of Contact Person	Jia Du
Designation	General Manager
Division Name of Contact Person	Quality Management
Contact Number	+86-755-89788050
Contact E-mail	Eva.du@adurochina.com
Date of Summary Prepared	07/Nov/2023

II. DEVICE DETAILS

Device Trade Name	Hygenix
Device Common Name	3 Ply Disposable Mask
Model(s)	Ear Loop
Device Classification name	Mask, Surgical
Regulation Number	21 CFR 878.4040
Device Class	Class II
Product Code	FXX

III. PREDICATE DEVICE DETAILS

Device Trade Name	Disposable Medical Face Mask (ear loop)
Device Manufacturer Name	Xiantao Topmed Nonwoven Protective Products Co., Ltd.

Model(s)	Ear Loop
510(k) Number	K221196
Regulation Number	21 CFR 878.4040
Device Class	Class II
Product Code	FXX

IV. DEVICE DESCRIPTION

The Hygenix is a 3 Ply flat- pleated and Disposable surgical mask. The inner and outer layers are made of spun-bond polypropylene, and the middle layer is made of melt blown polypropylene filter. The nose wire contained in the proposed device is in the layers of face mask to allow the user to fit the face mask around their nose, which is made of PC coated Aluminium wire.

The model ear loop is held in place over the user's mouth and nose by two elastic ear loops welded to the facemask. The ear loops are made of Polyester and Spandex.

The dimensions of the Mask are: length- 175 ± 5 mm and width- 95 ± 5 mm. These masks are single-use, disposable devices, provided non-sterile.

V. INDICATIONS FOR USE

The Hygenix is intended to be worn to protect both the patient and health care 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 device is disposable, non-sterile and for single use only.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Table 1: General Comparison

Sl. No	Features compared	Proposed Device	Predicate Device	Result
General Information				
1.	510(k) Number	K232797	K221196	-
2.	Manufacturer	Shenzhen Hygenix Industrial Co., Ltd	Xiantao Topmed Nonwoven Protective Products Co., Ltd.	-
3.	Common Name	3 Ply Disposable Mask	Disposable Medical Face Mask (ear loop)	Same

Sl. No	Features compared	Proposed Device	Predicate Device	Result
4.	Classification Name	Mask, Surgical	Mask, Surgical	Same
5.	Classification and Regulation number	Class II, 21 CFR 878.4040	Class II, 21 CFR 878.4040	Same
6.	Product Code	FXX	FXX	Same
7.	Indications For Use	The Hygenix is intended to be worn to protect both the patient and health care 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 device is disposable, non-sterile and for single use only.	The Disposable Medical 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
8.	Model specifications	3 ply flat-pleated masks with ear loops	Ear loop, Flat pleated,3 layers	Same
Materials				
9.	Outer layer	Spun bond Polypropylene (SBPP)	Spun bond Polypropylene	Same
10.	Filter layer	Melt Blown Polypropylene (MBPP)	Melt Blown Polypropylene	Same
11.	Inner layer	Spun bond Polypropylene (SBPP)	Spun bond Polypropylene	Same
12.	Nose wire	PC coated Aluminium wire	Galvanized iron wire coated by PE	Similar
13.	Ear loop	Polyester and Spandex	Polyester + Spandex	Same
14.	Mask color	Blue	Blue	Same
15.	Dimensions	Length- 175 ± 5 mm Width- 95 ± 5 mm	Length- 175 ± 5 mm Width- 95 ± 5 mm	Same

Sl. No	Features compared	Proposed Device	Predicate Device	Result
16.	OTC Use	Yes	Yes	Same
17.	Sterility	Non-sterile	Non-sterile	Same
18.	Reusability	Single use	Single use	Same
19.	ASTM F2100 Level	Level 3	Level 3	Same
Non-Clinical Testing				
20.	Fluid resistance	Pass at 160 mmHg	Pass at 160 mmHg	Same
21.	Flammability	Class 1	Class 1	Same
22.	Particulate Filtration Efficiency (PFE)	≥ 98%	≥ 98%	Same
23.	Bacterial Filtration Efficiency (BFE)	≥ 98%	≥ 98%	Same
24.	Differential pressure (ΔP)	< 6.0 mm H_2O/cm^2	< 6.0 mm H_2O/cm^2	Same
25.	Biocompatibility Testing	Non-cytotoxic Non-irritating Non-sensitizing	Non-cytotoxic Non-irritating Non-sensitizing	Same

VII. SUMMARY OF NON-CLINICAL TESTING

Performance Tests

Hygenix is subjected to the following performance tests according to the requirements provided in the guidance **Surgical Masks - Premarket Notification [510(k)] Submissions**.

- Fluid resistance
- Bacterial filtration efficiency
- Particulate filtration efficiency
- Differential pressure
- Flammability

ASTM F2100-19 Standard Specification for Performance of Materials Used in Medical Face Masks

ASTM F2101-19 Standard Test Method For Evaluating The Bacterial Filtration Efficiency (BFE) Of Medical Face Mask Materials, Using A Biological Aerosol Of Staphylococcus Aureus.

ASTM F2299 / F2299M - 03(2017) Standard Test Method for Determining the Initial Efficiency of Materials Used in Medical Face Masks to Penetration by Particulates Using Latex Spheres

EN 14683 (Annex C): 2019 Medical Face Masks – Requirements And Test Methods

ASTM F1862/F1862M-17 Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity)

16 CFR 1610 Standard for the Flammability of clothing textiles

Biocompatibility

The materials used in the Hygenix is biocompatible based on the biocompatibility tests mentioned in the guidance **Surgical Masks - Premarket Notification [510(k)] Submissions**:

- In-vitro Cytotoxicity
- Skin irritation
- Skin Sensitization

These tests are performed according to **ISO 10993-1:2018**, Biological Evaluation of Medical Devices - Part 1, Evaluation and Testing within a Risk Management Process.

ISO 10993-5:2009 Biological Evaluation Of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity.

ISO 10993-10:2010 Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization.

Table 2: Test Summary

Sl. No	Purpose	Reference Standard	Acceptance criteria	Result
1.	Fluid resistance	ASTM F1862/ F1862M-17	Pass at 160 mmHg	Pass at 160 mmHg
2.	Particulate Filtration Efficiency (PFE)	ASTM F2299 / F2299M - 03(2017)	≥ 98%	>98% Pass
3.	Bacterial Filtration Efficiency (BFE)	ASTM F2101-19	≥ 98%	> 98% Pass
4.	Differential pressure (ΔP)	EN 14683 (Annex C): 2019	< 6.0 mm H_2O/cm^2	< 6.0 mmH_2O/cm^2 Pass

Sl. No	Purpose	Reference Standard	Acceptance criteria	Result
5.	Flammability	16 CFR 1610	Class 1	Class 1 Pass
6.	In-vitro Cytotoxicity	ISO 10993-5:2009	Non-cytotoxic	Pass
7.	Skin Irritation	ISO 10993-10:2010	Non-irritating	Pass
8.	Skin Sensitization	ISO 10993-10:2010	Non-sensitizing	Pass

VIII. Clinical Test Data

No clinical study is included in this submission.

IX. CONCLUSION

The conclusions drawn from the nonclinical tests demonstrate that the proposed device is as safe, as effective, and performs as well as or better than the legally marketed predicate device.