July 28, 2021

Chuzhou Daddy's Choice Science and Technology Co., Ltd.
% Nickita Alexiades
Official Correspondent
mdi Consultants, Inc.
55 Northern Blvd., Suite 200
Great Neck, New York 11021

Re: K210856
Trade/Device Name: Purism Disposable Surgical Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical apparel
Regulatory Class: Class II
Product Code: FXX
Dated: July 6, 2021
Received: July 12, 2021

Dear Nickita Alexiades:

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 Clarence W. Murray, III, PhD
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)*
K210856

Device Name
Purism Disposable Surgical Mask

Indications for Use *(Describe)*
The Purism Disposable Surgical 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, 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

The assigned 5l0(k) number is K210856

1. Submitter's Identification:

Manufacturer: Chuzhou Daddy's Choice Science and Technology Co., Ltd.
Address: Middle of Nanjing Road,Langya District,Chuzhou City,Anhui, China

Contact Person: Chaozhong Song
Tel: +8618310114997
Email: scz1976@163.com

Date Summary Prepared: March 18, 2021

Official Correspondent: Mr. Nickita Alexiades
Mdi Consultants, Inc.
Address: 55 Northern Blvd. Suite 200, Great Neck, NY, United States
Tel: 201-220-2152
Email: nickita@mdiconsultants.com

2. Name of the Device:

Device Trade Name: Purism Disposable Surgical Mask
Classification Name: Surgical Face Mask
Regulatory Class: II
Product Code: FXX
Regulation Name: Surgical Apparel
Regulation Number: 878.4040

3. Information for the 510(k) Cleared Device (Predicate Device):

K182514
Disposable Surgical Face Mask
Xiantao Zhibo Non-woven Products Co., Ltd

4. Device Description:

The Purism Disposable Surgical Masks are manufactured with 3 layers, the inner facing layer and outer facing layer are composed of non-woven fabric, the middle layer is made up of melt-blown fabric. The surgical masks are single use, flat-folded with ear loops. The model of proposed device, ear loops, is held in place over the users' mouth and nose by two elastic ear loops welded to the face mask. The elastic ear loops are not made with natural rubber latex. The Surgical Masks are sold non-sterile and are intended to be disposable mask.

5. Indications for Use:

The Purism Disposable Surgical 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, provided non-sterile.

6. Technological Characteristics Comparison:

Table 1: Technological Characteristics Comparison

Device		Proposed device	Predicate device	Result
510(k)		K210856	K182514	-
Manufacturer		Chuzhou Daddy's Choice Science and Technology Co., Ltd	Xiantao Zhibo Non-woven Products Co., Ltd	-
Product Name		Purism Disposable Surgical Mask	Surgical Face Mask	Similar
Classification		Class II Device FXX (21 CFR878.4040)	Class II Device FXX (21 CFR878.4040)	Similar
Indications for Use		The Purism Disposable Surgical 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, 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.	Similar
Material	Outer facing Layer	Spun-bond polypropylene	Spun-bond polypropylene	Similar
	Middle layer	Melt blown polypropylene filter	Melt blown polypropylene filter	Similar
	Inner facing layer	Spun-bond polypropylene	Spun-bond polypropylene	Similar
	Nose piece	Polyethylene and iron wire	Malleable aluminum wire	Similar

	Ear loops	Nylon / Polyurethane composites	Polyester	Similar
Model		Ear loops 3-layers Flat Pleated	Ear loops 3-layers Flat Pleated	Similar
Color		Blue	White	Different
Dimension(width)		17.5cm±0.5cm	17.5cm±1cm	Similar
Dimension(length)		9.5cm±0.5cm	9.5cm±1cm	Similar
OTC use		Yes	Yes	Similar
Sterility		Non-sterile	Non-sterile	Similar
Use		Single Use, Disposable	Single Use, Disposable	Similar
ASTM F2100 Level		Level 3	Level 2	Similar
Non-Clinical Testing		ASTM F1862 ASTM F2299 ASTM F2100 ASTM F2101 EN14683 16 CFR 1610	ASTM F1862 ASTM F2299 ASTM F2100 ASTM F2101 16 CFR 1610	Similar
Biocompatibility Testing		Cytotoxicity Irritation Sensitization	Cytotoxicity Irritation Sensitization	Similar

7. Summary of Non-Clinical Tests:

The following testing was conducted to demonstrate that the subject device met the acceptance criteria or the performance specification of the test methodology or standard provided in the tables below:

Table 2 Non-clinical tests

Performance Testing Standard	Purpose	Acceptance Criteria	Results
Fluid Resistance Performance ASTM F1862	To evaluate the resistance of medical face masks to penetration by the impact of a small volume (~2 mL) of a high-velocity stream of synthetic blood.	At least 29 out of 32 specimens per lot show passing results at 160 mmHg	94 out of 96 pass at 160mmHg
Particulate Filtration Efficiency ASTM F2299	To determine the Initial Efficiency of Materials Used in Medical Face Masks to Penetration by Particulates Using Latex. Spheres	≥ 98% Average PFE for all samples tested	96/96 Samples Pass at Average of 99.90%
Bacterial Filtration Efficiency ASTM F2101	To measure the bacterial filtration efficiency (BFE) of medical face mask materials, employing a ratio of the upstream bacterial challenge to downstream residual concentration to determine filtration efficiency of medical face mask materials.	≥ 98% Average BFE for all samples tested	96/96 Samples Pass at Average of 99.88%
Differential Pressure (Delta P) EN 14683	To determine the pressure required to breathe through the final manufactured face mask.	Samples must be < 6.0 mm H_2O/cm^2	96/96 Samples Pass at Average of 4.1mmH2O/cm2
Flammability 16 CFR 1610	The purpose of this standard is to reduce danger of injury and loss of life by providing, on a national basis, standard methods of testing and rating the flammability of textiles and textile products for clothing use, thereby prohibiting the use of any dangerously	All samples must be Class I	96/96 Samples Pass for Class 1

	flammable clothing textiles.		

Table 3 Biocompatibility testing

Performance testing (Biocompatibility)	**Purpose**	**Acceptance Criteria**	**Results**
Cytotoxicity ISO 10993-5: Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	Under the research conditions, determine whether the target device extract is cytotoxic.	The sample is non-cytotoxic.	Under the conditions of the study, the device is noncytotoxic.
Irritation ISO 10993-10: Biological evaluation of medical devices -Part 10: Tests for irritation and skin sensitization	Under the research conditions, determine whether the non-polar and polar extracts of the target device are sensitive.	The sample is non-irritating.	Under the conditions of the study, the device is nonirritating.
Sensitization ISO 10993-10: Biological evaluation of medical devices-Part 10: Tests for irritation and skin sensitization	Under the research conditions, determine whether the non-polar and polar extracts of the target device are irritating.	The sample is non-sensitizing.	Under the conditions of the study, the device is non-sensitizing

8. Discussion of Clinical Tests Performed:

No clinical study is included in this submission.

9. Conclusions:

Based on the nonclinical tests performed, the subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate device, Xiantao Zhibo Medical Product Disposable Face Mask cleared under K182514.