July 22, 2021

Zhuhai Herald Datanetics 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: K210391
Trade/Device Name: Single-use medical face mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: June 11, 2021
Received: June 17, 2021

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); 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, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K210391

Device Name
Single-use medical face mask (Model: HD0969)

Indications for Use *(Describe)*
The Single-use medical face mask 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, 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.

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510(k) Summary

510(k) Summary

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

Subject Device: Single-use medical face mask (Model: HD0969)
510(k) Number: K210391

1. Date of the summary prepared: July 22, 2021

2. Submitter's Information
510(k) Owner's Name: Zhuhai Herald Datanetics Limited.
Establishment Registration Number: Applying
Address: Building#2, No.1 Pingxi Road 6, Nanping Science and Technology Industrial Park, Zhuhai, Guangdong, China
Contact Person: Jackson Leung
Email: jacksonleung@heraldata.com

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@share-info.com

3. Subject Device Information
Type of 510(k): Traditional
Classification Name: Surgical Face Mask
Trade Name: Single-use medical face mask
Model Name: HD0969
Review Panel: Surgical Apparel
Product Code: FXX
Regulation Number: 878.4040
Regulatory Class: 2

4. Predicate Device Information
Sponsor: DemeTECH Corporation
Trade Name: DemeMASK Surgical Mask
Classification Name: Surgical Face Mask
510(K) Number: K201479
Review Panel: Surgical Apparel
Product Code: FXX
Regulation Number: 878.4040
Regulation Class: 2

5. Indications for Use

The Single-use medical face mask 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, provided non-sterile.

6. Device Description

The Single-use medical face mask is flat pleated style mask, utilizing ear loops way for wearing, and they all has nose clip design for fitting the face mask around the nose.

The proposed device(s) are manufactured with three layers, the inner and outer facing layers are made of spunbonded non-woven, and the middle layer is made of melt-blown non-woven 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 nose clip contained in the proposed device(s) is in the layers of face mask to allow the user to fit the mask around their nose, which is made of PE coated Tin-plate wire.

The proposed device(s) are sold non-sterile and are intended to be single use, disposable device.

7. Summary of Technological Characteristics

Provided below is a comparison of the subject device and predicate device.

Elements of Comparison		Subject Device	Predicate Device	Result
Company		Zhuhai Herald Datanetics Limited.	DemeTECH Corporation	--
510 (k) Number		K210391	K201479	--
Trade Name		Single-use medical face mask	DemeMASK Surgical Mask	--
Classification Name		Surgical Face Mask	Surgical Face Mask	Same
Classification		Class II Device, FXX (21 CFR 878.4040)	Class II Device, FXX (21 CFR 878.4040)	Same
Indication for use		The Single-use medical face mask 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, provided non-sterile.	The Disposable 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 provided nonsterile.	Same
Material	Outer facing layer	Spun-bonded non-woven	Spun-bond polypropylene	Similar Note 1
	Middle layer	Melt-Blown non-woven	Melt blown polypropylene filter	Similar Note 1
	Inner facing	Spun-bonded non-woven	Spun-bond polypropylene	Similar Note 1

Elements of Comparison		Subject Device	Predicate Device	Result
	layer			
	Nose clip	PE coated Tin-plate wire	Galvanized wire coated with polyethylene	Similar Note 1
	Ear loops	Spandex	Spandex and Nylon – Not made from natural rubber latex	Similar Note 1
Color		white + blue	Not Applicable	Similar Note 1
Dimensions		175mm×95mm	Length: 17.5 cm±1 cm Width: 9.5 cm±1 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 3	Level 3	Same
Fluid Resistance Performance		Pass at 160 mmHg	Pass at 160 mmHg	Same
Particulate Filtration Efficiency		≥ 98%	Pass at ≥99%	Similar Note 2
Bacterial Filtration Efficiency		≥ 98%	Pass at ≥99%	Similar Note 2
Differential Pressure		On average of 4.7 mmH_2O/cm^2	Average 3.6 mmH_2O/cm^2	Similar Note 2
Flammability		Class 1	Class 1	Same

Comparison in Detail(s):

Note 1:

Although the “Material” “Color” and “Dimensions” of subject device are slightly difference with predicate device, it meets the requirement standard ASTM F2100, ASTM F1862, ASTM F2101, and ISO 10993.

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.

Summary of Non-Clinical Performance Testing

Performance Testing summary

Test Methodology	Purpose	Acceptance Criteria for Level 3	Test Results
Fluid Resistance Performance (mmHg) ASTM F1862	In order to verify whether the subject equipment meets the performance requirements of ASTM F2100 level 3.	Pass at 160mmHg	PASS Average of 3 batch numbers: 160mmHg
Particulate Filtration Efficiency Performance (%) ASTM F2299	In order to verify whether the subject equipment meets the performance requirements of ASTM F2100 level 3.	≥ 98%	PASS Average of 3 batch numbers: 98.79%
Bacterial Filtration Efficiency Performance (%) ASTM F2101	In order to verify whether the subject equipment meets the performance requirements of ASTM F2100 level 3.	≥ 98%	PASS Average of 3 batch numbers: 99.87%
Differential Pressure (Delta-P) (mmH_2O/cm^2) MIL-M-36954C	In order to verify whether the subject equipment meets the performance requirements of ASTM F2100 level 3.	<6.0 mmH_2O/cm^2	PASS Average of 3 batch numbers: 4.7 mmH_2O/cm^2
Flammability Class 16 CFR 1610	In order to verify whether the subject equipment meets the performance requirements of ASTM F2100 level 3.	Class 1	PASS Class 1

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

8. Summary of Clinical Performance Test
No clinical study is included in this submission.

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