September 18, 2020

Unisources Group LLC
% Rafael Aguila
Responsible Third-Party Official
Accelerated Device Approval Services, LLC
6800 S.W. 40th Street, Ste. 403
Ludlum, Florida 33155

Re: K202463
Trade/Device Name: Disposable Surgical Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical apparel
Regulatory Class: Class II
Product Code: FXX
Dated: August 26, 2020
Received: August 27, 2020

Dear Rafael Aguila:

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 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202463

Device Name

Disposable Surgical Mask

Indications for Use *(Describe)*
The Disposable Surgical Mask, FILTECH M201 is intended to be worn to protect both the patient and health care personnel from transfer of microorganisms, body fluids and particulate material. The disposable surgical mask is 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

[As required by 21 CFR 807.92]

1. Submission Information:

510(k) Number:	K202463
Date:	September 18th, 2020
Type of 510(k) Submission:	Traditional
Basis for 510(k) Submission:	New device
Applicant/US importer:	UNISOURCES GROUP LLC 7460 NW 52 street, Miami, Florida, 33166, USA
Manufacturer:	HANGZHOU FILTECH INTELLIGENT CO., LTD Room 302, Building 9, No. 360 Tianmushan West Road, Yuhang Street, Yuhang District, Hangzhou, Zhejiang, China 311121
Contact person:	Doris Dong [Consultant, from Shanghai CV Technology Co., Ltd.] Add: Room 903, No. 19 Dongbao Road, Songjiang Area, Shanghai, 201613 China E-mail: doris.d@ceve.org.cn Tel: 86 21-31261348 / Fax: 86 21-57712250

2. Device Description:

Proprietary Name:	Disposable Surgical Mask
Model	FILTECH M201
Common Name:	Surgical mask
Classification Name:	Mask, Surgical
Regulation Number:	878.4040
Product Code:	FXX
Device Class:	II
Review Panel:	General Hospital

3. Predicate device

Surgical Face Mask, K182515

WUHAN DYMEX HEALTHCARE CO., LTD

This predicate has not been subject to a design-related recall.

No reference devices were used in this submission.

4. Device Description

FILTECH M201 Disposable Surgical Mask is a single use, three-layer, flat-pleated mask with ear loops and a nose piece. The Disposable Surgical Mask is manufactured with three layers, of which the inner and outer layers are made of spun-bond polypropylene, and the middle layer is made of melt blown polypropylene filter. The ear loops are 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 latex materials, but are made of spandex. The nose piece in the layers of face mask allows the user to fit the face mask around their nose, which is made of malleable polyethylene wire. The surgical mask will be provided in blue of outside and white of inside. FILTECH M201 Disposable Surgical Mask is provided non-sterile and for single use.

5. Indication for use

The Disposable Surgical Mask, FILTECH M201 is intended to be worn to protect both the patient and health care personnel from transfer of microorganisms, body fluids and particulate material. The Disposable Surgical Mask is 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. Comparison of technological characteristics with the predicate device:

Table 1 General comparison

Device	Proposed device	Predicate device	Result
510(k) Holder	UNISOURCES GROUP LLC	WUHAN DYMEX HEALTHCARE CO., LTD	--
510(k) Number	K202463	K182515	--
Name	Disposable Surgical Mask	Surgical Face Mask	--
Model	FILTECH M201	/	--
Classification	Class II Device, FXX (21 CFR 878.4040)	Class II Device, FXX (21 CFR 878.4040)	Same
Intended use	The Disposable Surgical Mask, FILTECH M201 is intended to be worn to protect both the patient and health care personnel from transfer of microorganisms, body fluids and particulate material. The Disposable Surgical Mask is 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
Mask style	Flat Pleated	Flat Pleated	Same
Design	Ear loop	Ear loop	Same
Layers	Three	Three	Same
Color	Blue outside; white inside	Yellow	Similar Note 1
Target population	Adults	Adults	Same
Dimension (Length)	175mm±5mm	17.5cm±0.2cm	Similar Note 2
Dimension (Width)	95mm±5mm	9.5cm±0.2cm	
Sterility	Non-sterile	Non-sterile	Same
Use	Single use, disposable	Single use, disposable	Same
Anatomical site	Nose and mouth	Nose and mouth	Same
Technology	Self-suction filter mask	Self-suction filter mask	Same
Environment of use	OTC	OTC	Same
Material			
Outer facing layer	Spunbond polypropylene	Spunbond polypropylene	Same
Middle layer	Melt blown polypropylene filter	Melt blown polypropylene filter	Same

Inner facing layer	Spunbond polypropylene	Spunbond polypropylene	Same
Ear loops	Spandex	Spandex	Same
Nose piece	Malleable polyethylene wire	Malleable polyethylene wire	Same
Colorants	Polypropylene (PP) master batch	Unknown	Similar Note 1
ASTM F2100 Level	Level 2	Level 2	Same
Biocompatibility (limited contact (<24h) surface devices on intact skin)			
Cytotoxicity	Under the conditions of the study, the proposed device extract was determined to be non-cytotoxic.	Under the conditions of the study, the predicate device extract was determined to be non-cytotoxic.	Same
Irritation	Under the conditions of the study, the proposed device non-polar and polar extracts were determined to be non-irritating.	Under the conditions of the study, the predicate device non-polar and polar extracts were determined to be non-irritating.	Same
Sensitization	Under the conditions of the study, the proposed device non-polar and polar extracts were determined to be non-sensitizing.	Under the conditions of the study, the predicate device non-polar and polar extracts were determined to be non-sensitizing.	Same
Differences between New device and Predicate Device:			
Note 1: The difference in color does not raise additional questions for safety and effectiveness. Biocompatibility evaluation has been performed on the final finished device which includes all construction materials and color additives. **Note 2:** The tolerance of dimension are a little different between proposed device and predicate device. By investigating similar legally market products, the tolerance of 5mm is acceptable for surgical face mask. And performance testing results demonstrate that our proposed device meet the expected requirements. Therefore this difference doesn't raise any new safety and effectiveness issues.			

7. Non-clinical test performed on the proposed device:

The proposed device was tested and conformed to the following standards and requirements stated in guidance for industry passed and FDA Staff Surgical Masks – Premarket Notification [510(k)] Submission issued on March 5, 2004:

Table 2 Performance Testing

Performance tests	Proposed device	Predicate device	Acceptance Criteria	Result
Fluid Resistance Performance ASTM F1862	32 out of 32 pass at 120mmHg	32 out of 32 pass at 120mmHg	29 out of 32 pass at 120mmHg	Same
Particulate Filtration Efficiency ASTM F2299	98%	99.7%	≥ 98%	Similar
Bacterial Filtration Efficiency ASTM F2101	99.6%	99.9%	≥ 98%	Similar
Differential Pressure (Delta-P)	5.5mmH_2O/cm^2	4.0mmH_2O/cm^2	< 6.0mmH_2O/cm^2	Similar

MIL-M-36954C				
Flammability class 16CFR 1610	Class 1	Class 1	Class 1	Same

8. Clinical test conclusion

No clinical study is included in this submission.

9. Conclusion

The conclusion drawn from the nonclinical tests demonstrate that the subject device is as safe, as effective, and performs as well as the legally marketed predicated K182515.