February 19, 2022

Heartland Health Products
Frank Fischer
Chief Operating Officer
5389 East Provident Dr
Cincinnati, Ohio 45246

Re: K212366
Trade/Device Name: Heartland Health Surgical Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: January 25, 2022
Received: January 25, 2022

Dear Frank Fischer:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212366

Device Name
Heartland Health Surgical Mask

Indications for Use *(Describe)*
The surgical 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Date of Summary Prepared: 01/21/2022

510(k) Number: K212366

Submitted by:

Company Name:	Heartland Health Products
Company Address:	5389 East Provident Dr Cincinnati, OH 45246
Contact Person:	Frank Fischer, Chief Operating Officer
Phone:	513-870-1611
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Correspondent:	Doug Keefe, Quality/Regulatory Manager
Correspondent Phone:	513-870-1611
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Regulatory Information:

Trade Name:	Heartland Health Surgical Mask
Common/Usual Name:	Surgical mask
Product Code:	FXX
Regulation Number:	21 CFR 878.4040
Device Class:	Class II
Reviewing Panel:	General Hospital
Basis for Submission:	New device abbreviated 510(k)

Predicate Device:

510(k) Number:	K131879
510(k) Holder:	Kimberly-Clark*
Device Name:	Surgical mask

Indications for Use:

The surgical 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.

Device Description:

The surgical mask is a three-layer, flat pleated facepiece composed of a spunbond outer layer, filter layer, and spunbond (skin-contacting) inner layer. The mask is held in place with an elastic headband, and the position of the mask on the face is maintained with a nose wire and elastic beneath the chin. It is supplied non-sterile and is a single-use disposable.

Summary of Comparison and Technological Characteristics

Table 1. Predicate Comparison **Description**	**Subject Device**	**Predicate (K131879)**	**Comparison**
Indication for Use	The surgical 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 Kimberly-Clark KC300 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.	Same
Environment of Use	OTC	OTC	Same
Sterility	Non-sterile	Non-sterile	Same
Use	Single-use, disposable	Single-use, disposable	Same
Anatomical site	Nose and mouth	Nose and mouth	Same
Target Population	Adults	Adults	Same
Design Features			
Mask style	Flat-pleated	Flat-pleated	Same
Design	Headband	Ear loops, tie strings	Different, but no new issues of safety or efficacy
Materials			
Outer facing layer	Polypropylene spunbond	Polyethylene/polyester with pink and blue ink	Similar, both met performance and biocompatibility requirements
Middle layer	Polypropylene	Polypropylene spunbond, polypropylene meltblown	Same
Inner facing layer	Polypropylene spunbond	Polyethylene/polyester	Similar, both met performance and biocompatibility requirements

Table 1. Predicate Comparison **Description**	**Subject Device**	**Predicate (K131879)**	**Comparison**
Chin elastic	Lycra	N/A	Different. both met performance and biocompatibility requirements
Nose piece	Polyethylene and soft annealed carbon steel	Unknown	Similar. both met performance and biocompatibility requirements
Headband materials	Spunbond polypropylene, spandex with blue ink	Polyester/Lycra knitted	Similar, both met performance and biocompatibility requirements
Colorants	Aquaking Pro Cyan (headband)	Markem Ink (facepiece)	Different, both met biocompatibility requirements
Specifications and Dimensions			
Layers	Three	Multiple	Similar
Dimension (length)	241 ± 7mm (9.5" ± .28") (small) 279 ± 7mm (11" ± .28") (large)	6.5" ± 0.75"	Different, but no new issues of safety or efficacy
Dimension (width)	105 ± 6 mm (3.7" ± 0.24") (small and large)	4" ± 0.75"	Similar, but no new issues of safety or efficacy
Color	white (facepiece) blue (headband)	Pink and blue (facepiece)	Different, both met biocompatibility requirements
Testing			
NIOSH Certification number	N/A	N/A	Same
ASTM F2100-19 Level	Level 3	Level 3	Same
Biocompatibility (ISO 10993)	Non-cytotoxic, Non-sensitizing, Non-irritating	Non-cytotoxic, Non-sensitizing, Non-irritating	Same

Non-clinical Tests Performed on the Proposed Device

Non-clinical testing was conducted in accordance with FDA's "Guidance for Industry and FDA Staff Surgical Masks – Premarket Notification [510(k)] Submission," issued March 5, 2004. A summary of performance testing, including references to recognized standards, is provided below in Table 2.

Table 2: Summary of Non-Clinical Testing

Test Methodology	Purpose	Acceptance Criteria	Results
ASTM F1862:2017- Fluid Resistance Performance	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.	Class 3 - pass at 160mmHg Class 2 - pass at 120mmHg Class 1- pass at 80mmHg	Pass
ASTM F2299:2017 - Particulate Filtration Efficiency	Evaluate filtration efficiency by comparing the particle count in the feed stream (upstream) to that in the filtrate (downstream) for the materials used in medical face masks	$>98\%$	Pass
ASTM F2101:2019 - Bacterial Filtration Efficiency	Evaluate the effectiveness of medical face mask materials in preventing the passage of aerosolized bacteria, expressed in the percentage of a known quantity that does not pass the medical face mask material at a given aerosol flow rate.	$>98\%$	Pass
EN 14683:2019 - Differential Pressure	Evaluate the resistance to air flow and breathability of a medical face mask by measuring differential pressure through the materials of a mask	$<6.0 mmH_2O/cm^2$	Pass
16 CFR 1610 - Flammability	Evaluate the resistance of a mask to ignition when exposed to a flame	Class 1	Pass
ISO 10993-5:2009, Cytotoxicity	Evaluate the potential of a medical device to cause cytotoxic reactions in mammalian cell culture	Under the conditions of the study, the predicate device extract was determined to be non-cytotoxic	Pass
ISO 10993-10: 2021, Irritation	Evaluate the potential of a medical device to cause skin irritation	Under the conditions of the study, the predicate device non-polar and polar extracts were determined to be non- irritating.	Pass

ISO 10993-10:2021, Sensitization	Evaluate the potential of a medical device to cause skin sensitization	Under the conditions of the study, the predicate device non-polar and polar extracts were determined to be non-sensitizing.	Pass

Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the proposed device in 510(K) submission K212366, Heartland Health Surgical Mask is as safe, as effective and performs as well as or better than the legally marketed predicate device (K131879), Kimberly-Clark KC300 Face Mask.