July 28, 2021

Honeywell Safety Products
Ivy Grieco
Senior Advanced Quality Engineer
10 Thurber Boulevard
Smithfield, Rhode Island 02917

Re: K211497
Trade/Device Name: Surgical Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: May 11, 2021
Received: May 14, 2021

Dear Ivy Grieco:

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, Ph.D.
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)*

K211497

Device Name
Honeywell Procedure Mask

Indications for Use *(Describe)*

The Honeywell Procedure 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 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary
(K211497)

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

I. SPONSOR

Honeywell Safety & Productivity Solutions
10 Thurber Blvd.
Smithfield, RI 02917 USA

II. CONTACT PERSON

Ivy Grieco
Title: Sr. Adv. Quality Engineer
Phone: 401-864-0496
Email: Ivy.Grieco@Honeywell.com
Date Prepared: July 21, 2021

III. DEVICE

Name of Device: Honeywell Procedure Mask
Common or Usual Name: Procedure Mask
Classification Name: Surgical Apparel (21 CFR §878.4040)
Regulatory Class: II
Product Code: FXX

IV. PREDICATE DEVICE

Manufacturer: Changzhou Combat Protective Equipment Co., Ltd.
Device: Nordiwell Medical Face Mask
510(k) Number: K210445
This predicate has not been subject to a design-related recall.

V. DEVICE DESCRIPTION

The Honeywell Procedure Mask is composed of three layers that are a flat, pleated style mask with earloops to secure it over the users' mouth and face. The inner and outer layers are manufactured from spun-bond polypropylene. The middle layer is made of melt-blown polypropylene. The mask is a single use, disposable device, provided nonsterile and is not made from natural rubber latex.

VI. INDICATIONS FOR USE

The Honeywell Procedure 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 potential exposure to blood and body fluids. This is a single use, disposable device, provided non-sterile.

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Honeywell Procedure Mask is compared with the predicate device Nordiwell Medical Face Mask (K210445)). The results are shown below in the Technological Characteristics Comparison Table:

Item	**Subject Device** **Honeywell Procedure Mask**	**Predicate Device** **Nordiwell Medical Face Mask**	**Comparison**
510(k) Number	K211497	K210445	
Intended Use Statement	The Honeywell Procedure 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 potential exposure to blood and body fluids. This is a single use, disposable device, provided non-sterile.	The Nordiwell Medical Face Mask is intended to be worn to protect both patient and healthcare personnel from transfer of microorganisms, body fluids, and particulate matters. These face masks are intended for use in infection control practices to reduce potential exposure to blood and body fluids. This is a single use, disposable device(s) and provided nonsterile	Same
Materials			
Outer Layer	Polypropylene Spun-bond	Polypropylene Spun-bond	same
Middle Layer	Polypropylene Melt-blown	Polypropylene Melt-blown	same
Inner Layer	Polypropylene Spun-bond	Polypropylene Spun-bond	same
Earloop	Round Knit Polyester and Lycra	Spandex and Nylon	different
Nose Wire	Polyethylene Coated Steel Wire	Polyethylene Coated Steel Wire	same
Design Features			
Color	White	White	same
Style	Flat, Pleated	Flat, Pleated	same
Layers	3	3	same
Physical State	Single Use Only	Single Use Only	same
Sterility	Non-Sterile	Non-Sterile	same
Dimensions			
Length	173mm ± 3mm	160mm ± 5mm	different
Width	95mm ± 3mm	106mm ± 5mm	different
Performance Specifications & Testing			
ASTM Level	2	2	same
Fluid Resistance (ASTM F1862)	Passed at 120 mmHg	Passed at 120 mmHg	same
Particulate Filtration Efficiency (PFE)	Passed at ≥98% @ 0.1 micron	Passed at ≥98% @ 0.1 micron	same
Bacterial Filtration Efficiency (BFE)	Passed at ≥98%	Passed at ≥98%	same
Differential Pressure	Passed at <5.0 mmH^2O/cm^2	Passed at <5.0 mmH^2O/cm^2	same

Flammability (16 CFR 1610)	Class 1	Class 1	same
Biocompatibility			
Cytotoxicity	Non-Cytotoxic	Non-Cytotoxic	same
Skin Irritation	Non-Irritating	Non-Irritating	same
Dermal Sensitization	Non-Sensitizing	Non-Sensitizing	same

VIII. SUMMARY OF NON-CLINICAL TESTING

Performance Testing

Mask performance was tested to ASTM's F2100 standard. Each type of performance testing used 32 samples in each of 3 different, non-consecutive lots. Testing consisted of the following:

Test Methodology	Purpose	Acceptance Criteria	Results
ASTM F1862	Fluid Resistance/Synthetic Blood Penetration	120 mmHg	120 mmHg
ASTM F2299	Particulate Filtration Efficiency	≥98%	≥99.45% @ 0.1 micron
ASTM F2101	Bacterial Filtration Efficiency	≥98%	≥98.2% @ 3.0 micron
EN 14683 Annex C	Differential Pressure "Breathability"	<6.0 mmH_2O/cm^2	≤4.8 mmH^2O/cm^2
16 CFR Part 1610	Flammability	IBE or ≥3 seconds burn time, Class 1	IBE, Class 1

Biocompatibility testing

The biocompatibility evaluation for the Honeywell Procedure Mask device was conducted in accordance with the FDA's Guidance "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process'" September 2020, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The battery of testing included the following tests:

Test Methodology	Purpose	Acceptance Criteria	Results
ISO 10993-5	Cytotoxicity	Non-Cytotoxic	This device is non-cytotoxic
ISO 10993-10	Dermal Sensitization	Negligible	This device is not considered a contact sensitizer
ISO 10993-10	Skin Irritation	Negligible	This device is classified as negligibly irritating to the skin

IX. SUMMARY OF CLINICAL TESTING

Clinical testing is not needed for this device.

X. CONCLUSION

The proposed device has the same indication for use and similar technological characteristic as the predicate device. Non-clinical testing demonstrates that the proposed device performs as safe and effective as the predicate device.