November 10, 2022

Entreprise Prémont Inc.
Charlie Marchand
Director of Product Development and Compliance
731 Boulevard Saint Laurent Est
Louiseville, Quebec J5V 1J1
Canada

Re: K222551
Trade/Device Name: Humask Pro Vision 3000
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: August 15, 2022
Received: August 23, 2022

Dear Charlie Marchand:

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,

Brent Showalter -S

Brent Showalter, Ph.D.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic 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)*
K222551

Device Name
Humask Pro Vision 3000

Indications for Use *(Describe)*
The Humask Pro Vision 3000 mask is single use disposable intended to be worn in the operating room as well as dental, isolation, and other medical procedures to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids, and particulate material.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

I. SUBMITTER

Humask
731 Boulevard Saint Laurent Est
Louiseville, Quebec, J5V 1J1
Canada
Contact person: Charlie Marchand
Phone: 819-519-3255 ext.215
Date prepared: 31st of October 2022

II. DEVICE

Name of the device: Humask Pro Vision 3000
Common of usual name: Surgical Mask
Classification name: Surgical Mask
Regulatory Class: 2
Product Code: FXX
Regulation: 21 CFR 878.4040

III. PREDICATE DEVICE

Communicator (K152561)- primary predicate
The predicate has not been subject to a design-related recall.

IV. DEVICE DESCRIPTIONS

The Humask Pro Vision 3000 is a clear window surgical mask. A Medical grade face mask with a transparent window.

V. INDICATIONS FOR USE

The Humask Pro Vision 3000 mask is single use disposable intended to be worn in the operating room as well as dental, isolation, and other medical procedures to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids, and particulate material.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The technological characteristics of the Humask Pro Vision 3000 is highly analogous to the predicate device, the Communicator (K152561).

The similarities and differences are illustrated in the tables below:

Characteristics	Humask Pro Vision 3000	Communicator (K152561)

510(k) Summary

Indications for Use	The Humask Pro Vision 3000 mask is single use disposable intended to be worn in the operating room as well as dental, isolation, and other medical procedures to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids, and particulate material.	The Communicator Surgical Facemask with Clear Window, FM86000, is single use disposable intended to be worn in the operating room as well as dental, isolation, and other medical procedures to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids, and particulate material
Prescription Only or OTC	OTC	OTC

The indications for use statement for the subject device is functionally the same as the predicate device.

	Humask Pro Vision 3000	**PREDICATE Communicator (K152561)**	**Similarities/ differences**
Principle of Operation	Protective mask	` Protective mask	SAME
Single use	Yes	Yes	SAME
Mask Style	Surgical mask- flat, pleated	Surgical mask- flat, pleated	SAME
Design/ Const.			
Materials	• Polypropylene spun bond • PTFE laminated Polypropylene • 3ml steel wire (Noseband) • Spandex (ear loops) • Polyethylene plastic window	• Polypropylene bicomponent spun bond • Melt blown • Plastic window • Aluminum (Noseband)	DIFFERENT
Design features	Ear loops	Ear loops	SAME

	Humask Pro Vision 3000	PREDICATE Communicator (K152561)	Similarities/ differences
	Nose band Transparent window	Nose band Transparent window	
Transparent window shape	Rectangular	Diamond	DIFFERENT
Transparent window dimensions	4.9 in x 1.7 in	4.75 in x 1.35 in (tapering to 0.5 width)	DIFFERENT
How provided	Non-sterile	Non-sterile	SAME
Biocompatibility	ISO 10993	ISO 10993 (presumed)	SAME
Performance Data	ASTM F1862 ASTM F2101 ASTM F2299 EN 14683 16 CFR PART 1610 ISO 10993-5 ISO 10993-10	(Presumed – standard requirements) ASTM F1862 ASTM F2101 ASTM F2299 EN 14683 16 CFR PART 1610 ISO 10993-5 ISO 10993-10	SAME

The performance test data demonstrating compliance with those requirements outlined in FDA Guidance Surgical Masks Premarket Notification Submissions, May 2003.

The technological characteristics of the subject device are similar to the technological characteristics of the predicate. The fundamental difference is the nature of the filter media used within the mask and the size and shape of the window. The Predicate product's media filter is a melt blown material which is a polypropylene spun bound product electrostatically charged to trap particles coming through the filter. The HuCare™ membrane is comprised of (polytetrafluorethylene) PTFE film laminated onto a polypropylene spun bound sheet. The HuCare™ membrane is also smooth and non-pilling as well as hydrophobic which plays a role in the resistance to body fluids and evacuation of humidity that can accumulate within the mask throughout use. The size and shape of the window in this mask is also a differentiation point between the predicate mask and the Humask Pro Vision 3000 mask; The predicate product's window is in the shape of a diamond (4.75 in x 1.35 in (tapering to 0.5 width)) reaching its widest point in the middle of the mask. The Humask Pro Vision 3000's window is rectangular (4.9 in x 1.7 in) and longer than the predicate.

At a high level, the subject and predicate devices are based on the following same technological elements:

- Outer layers are polypropylene spun bound material

- Mask type is based on a flat pleated mask
- Window material is clear see-through plastic
- Ear loops and nose band for secure and comfortable wear
- Mask contains inner filter layer

The following differences exist between the subject and predicate devices:

- Window shape (Humask Pro Vision 3000 is rectangular and predicate is diamond shaped)
- Inner filter material (Humask Pro Vision 3000 uses HuCare membrane (laminated PTFE) and predicate uses melt blown)

VII. PERFORMANCE DATA

The following performance data support the substantial equivalence of the Humask Pro Vision 3000.

- Bacterial filtration efficiency (ASTM F2101)
- Particle filtration efficiency (ASTM F2299)
- Differential Pressure (EN 14683)
- Flammability (16 CFR PART 1610)
- Resistance to synthetic blood (ASTM F1862)
- ISO 10993-5 Cytotoxicity
- ISO10993-10 Allergenicity and sensitization

The subject devices met all specified criteria and did not raise new safety or performance questions. Based on the performance testing, the Humask Pro Vision 3000 was found to have a safety and effectiveness profile that is similar to the predicate device.

VIII. CONCLUSIONS

The Humask Pro Vision 3000 is substantially equivalent to the legally marketed predicate device.