September 9, 2022

PointCore, Inc.
% Mr. Dave McGurl
Senior Director, Regulatory Affairs
Mcra, LLC
803 7th Street, NW, 3rd Floor
Washington, District of Columbia 20001

Re: K220944
Trade/Device Name: PointCore Surgical Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: August 31, 2022
Received: September 8, 2022

Dear Mr. McGurl:

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, 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)*
K220944

Device Name
PointCore Surgical Mask

Indications for Use *(Describe)*
The PointCore 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 surgical 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.

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

Device Trade Name: PointCore Surgical Mask

Manufacturer:
PointCore, Inc.
124 SW Adams
Peoria, IL 61602
Phone: 309.404.4800

Contact:
Mr. Dave McGurl
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Prepared by:
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803 7th Street, NW, 3rd Floor
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Office: 202.552.5800

Date Prepared: August 31, 2022

Regulation Number: 21 CFR §878.4040

Regulation Name: Surgical Apparel

Regulatory Class: II

Product Code(s): FXX

Primary Predicate: SAN-M PACKAGE CO., LTD. Surgical Face Masks (Ear loops and Tie-on) (K160269)

Additional Predicate: N/A

Indications For Use:

The PointCore 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 surgical 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.

Device Description:

The PointCore Surgical Mask is a surgical mask with ear loops and nose piece for fitting and securing the mask to the to the user's face. The ASTM Level of the subject device is ASTM Level 2. The finished size of the mask is 175mm x 95 mm. The masks are comprised of three layers: an outer polyethylene/polyester layer, a meltblown nonwoven filter layer, and an inner polypropylene layer. The mask also includes an adjustable nose strip and flat or round elastic ear loop. The nosepiece is manufactured from a reinforced plastic piece with a metal insert.

Predicate Device:

PointCore submits the following information in this Premarket Notification to demonstrate that, for the purposes of FDA's regulation of medical devices, the PointCore Surgical Mask is substantially equivalent in indications, design principles, and performance to the following predicate devices, which have been determined by FDA to be substantially equivalent to pre-amendment devices:

Primary Predicate: SAN-M PACKAGE CO., LTD. Surgical Face Masks (Ear loops and Tie-on) (K160269)

Performance Testing Summary:

The following testing was completed for the subject device:

- Synthetic Blood Penetration Resistance
- Particle Filtration Efficiency
- Bacterial Filtration Efficiency
- Differential Pressure Test
- Flammability of Clothing Test

Substantial Equivalence:

Below is a summary table of the technological characteristics comparison between the subject and predicate devices.

Information	**PointCore Surgical Mask** ***Subject Device***	**Surgical Face Masks (Ear loops and Tie-on)** **SAN-M PACKAGE CO., LTD.** ***K160269***	**Comparison**
Classification	II	II	Identical
Regulation	878.4040	878.4040	Identical
Product Code	FXX	FXX	Identical
Indications	The PointCore Surgical Mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate	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	Identical

Information		PointCore Surgical Mask *Subject Device*	Surgical Face Masks (Ear loops and Tie-on) SAN-M PACKAGE CO., LTD. *K160269*	Comparison
		material. These surgical 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.	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.	
Materials	Inner Layer	Polyethylene/Polyester White	Polypropylene	Similar
	Outer Layer	Polypropylene	Polypropylene	
	Middle Layer/ Filter Layer	Meltblown Nonwoven White	Polypropylene spunbond Polypropylene meltblown	
	Ear Loops	Nylon/Spandex - Latex free	Ear loops: Polyester, polyurethane Side tapes: Polyester spunbond (ear loops mask only) Tie tapes: Polypropylene spunbond or polyester spunbond	
	Nose Piece	Reinforced plastic with metal insert	Polyethylene coated steel wire	
ASTM Level		Level 2	Level 1	Different
Dimensions		17.5 ± 0.5 cm x 9.5 ± 0.5 cm	• 17.5 ± 0.5 cm x 9 ± 0.3 cm • 18 ± 0.5 cm x 9 ± 0.3 cm	Similar
Color		White	White or Blue	Similar
Mask Style		Flat pleated, 3-ply	Flat pleated, 3-ply	Identical
Design Features		Ear loop	Ear loop	Identical
Sterility		Non-Sterile	Non-Sterile	Identical
Use		Single Use	Single Use	Identical

Information	PointCore Surgical Mask *Subject Device*	Surgical Face Masks (Ear loops and Tie-on) SAN-M PACKAGE CO., LTD. *K160269*	Comparison
Fluid Resistance	Passed acceptance criteria of ASTM F1862	Passed acceptance criteria of ASTM F1862	Identical
Particulate Filtration Efficiency	ASTM F2299	ASTM F2299	Identical
Bacterial Filtration Efficiency	ASTM F2101	ASTM F2101	Identical
Differential Pressure	MIL-M36945C	MIL-M36945C	Identical
Flammability	16 CFR 1610	16 CFR 1610	Identical
Biocompatibility	ISO 10993	ISO 10993	Identical

Conclusion:

The subject device and the predicate devices have the same intended use, have similar technological characteristics, and are made of similar materials. The subject and predicate devices are packaged in similar materials and are sterilized using similar methods. The data included in this submission demonstrate substantial equivalence to the predicate devices listed above. The PointCore Surgical Mask is as safe, as effective, and performs as well as, or better, than the predicate devices.