March 23, 2021

Plastikon Industries
℅ Mary Gallup
RA Consultant
Hantel Technologies, Inc
3496 Breakwater Ct
Hayward, California 94545

Re: K203064
Trade/Device Name: Surgical Mask, ASTM Level 2 or Level 3
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: February 12, 2021
Received: February 17, 2021

Dear Mary Gallup:

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,

Ryan Ortega, PhD
Acting 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)*
K203064

Device Name
Surgical Mask, ASTM Level 2 or Level 3

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 potential exposure to blood and body fluids. The face mask is 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 – K203064

Device Name:	Surgical Mask, ASTM Level 2 or Level 3
Sponsor Information:	Plastikon Industries 688 Sandoval Way Hayward, CA 94545
Contact person:	Paul Gutwald Title: Chief Operating Officer Phone Number: (510) 400-1010 Fax Number: (510) 400-1141 e-mail: pgutwald@plastikon.com
Date of Summary:	03/15/2021
Common Name:	Surgical Mask
Classification Name:	Surgical Apparel
Proprietary Name:	Surgical Mask – ASTM Level 2 or Level 3
Review Panel:	General and Plastic Surgery
Product Code:	FXX
Device Classification:	Class II per (21 CFR §878.4040)
Predicate Device:	San-M Package Co, K160269 Surgical Mask
Intended 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 potential exposure to blood and body fluids. The face mask is single use, disposable device, provided non-sterile.

Available Model Numbers

PLASMA Surgical-1	Surgical Mask

Device Description:

The surgical mask is composed of three-layers and are flat-pleated. The mask materials consist of an outer layer (polypropylene spunbond, white), filter middle layer (polypropylene melt-blown, white) and inner layer (spunbond polypropylene, white). Each mask contains ear loops to secure the mask over the users' mouth and face and includes a malleable nosepiece to provide a firm fit over the nose. The mask is a single use, disposable device, provided non-sterile.

The device is not made from Natural Rubber Latex.

Technological Characteristics:

The Surgical Mask is compared with the predicate device. The results are shown below in the Technological Characteristics Comparison Table:

Items(S)	Surgical Mask (K203064) Subject Device		Predicate Device (K160269) San-M Package Co. Surgical Face Masks			Comparison
	Level 2	Level 3	Level 1	Level 2	Level 3	
Intended Use/ 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. This face mask is 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 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 potential exposure to blood and body fluids. This is a single-use, disposable device, provided non-sterile.			Same
Materials						
Outer Material	Polypropylene Spunbond, White		Polypropylene			Same
Filter Web (Middle)	Polypropylene Meltblown, white		1. Polypropylene spunbond 2. Polypropylene meltblown			Same
Inner Material	Polypropylene Spunbond, white		Polypropylene			Same
Nose Clamp	Polyethylene Coated Steel Wire		Polyethylene coated steel wire			Same
Ear Loops / Tie Tapes	Elastic Laminate – No Tie Tapes		Ear loops: Polyester, polyurethane Side tapes: Polyester spunbond (ear loops mask only) Tie tapes: Polypropylene spunbond or polyester spunbond			Same – The subject device is an ear loop type attachment. The ear loop materials has been tested for biocompatibility and does not does not affect the device performance.
Design Features						
Colors	White (Outer)		• Colors: white or blue • Visor option: polyester			Different The subject device does not

				come in any other colors. The color of the device does not affect the device performance or Biocompatibility as demonstrated by the test results.
Style	Flat - Pleated	Flat - Pleated		Same
Multiple Layers	Yes	Yes		Same
Single Use	Yes	Yes		Same
Sterility				
Sterile	Non-Sterile	Non-Sterile		Same
Dimensions				
Length	95 +/- 19mm	90 +/- 3mm	90 +/- 3mm	Same
Width	175 +/- 19mm	175 +/- 5mm	180 +/- 5mm	Same

Performance Testing (ASTM F2100)	**Subject Device**		**Predicate Device**			**Comparison**
	Level 2	**Level 3**	**Level 1**	**Level 2**	**Level 3**	
Fluid Resistance ASTM F1862-17	Pass @ 120 mmHg	Pass @ 160 mmHg	Pass @ 80 mmHg	Pass @ 120 mmHg	Pass @ 160 mmHg	Same
Particulate Filtration Efficiency (PFE) ASTM F2299	Pass @ 99.8%	Pass @ 99.8%	Pass @ 99.6%	Pass @ 99.6%	Pass@ 99.7%	Different The subject device has slightly higher or improved particulate efficiency. This does not increase risk associated with the use of the device
Bacterial Filtration Efficiency (BFE) ASTM F2101-19	Pass @ >99%	Pass @ >99%	Pass @ >98%	Pass @ >98%	Pass @ >98%	Different The subject device has slightly higher or improved BFE. This does not increase risk associated with the use of

						the device
Differential Pressure EN 14683:2019 Annex C	Pass @ 5.1mm H_20/cm^2	Pass @ 5.1mm H_20/cm^2	Pass @ 2.0mm H_20/cm^2	Pass @ 1.0mm H_20/cm^2	Pass@ 2.5 mm H_20/cm^2	Different The subject device has higher differential pressure, and continues to meet the standard for ASTM classification for 2 and 3. This does not increase risk associated with the use of the device
Flammability 16 CFR Part 1610	Class 1	Class 1	Class 1	Class 1	Class 1	Same

Biocompatibility			
Test	**Subject Device**	**Predicate Device**	**Comparison**
Cytotoxicity	Non-cytotoxic	Non-cytotoxic	Same
Irritation	Non-irritating	Non-irritating	Same
Sensitization	Non-sensitizing	Non-sensitizing	Same

Non-Clinical Performance Testing

The surgical mask has been tested according to ASTM 2100-19 – Standard Specification for Performance of materials used in Medical Face Masks, and meets the requirements to be designated as ASTM Level 2 or Level 3, and have met the requirements for biocompatibility.

Standard	**Performance Characteristics, Level 2, 3**	**Surgical Mask**
ASTM F1862-17	Resistance to Penetration by Synthetic Blood	Passed
ASTM F2299	Particulate Filtration Efficiency (PFE)	Passed
ASTM F2101-19	Bacterial Filtration Efficiency (BFE)	Passed
EN 14683:2019 Annex C	Differential Pressure	Passed
16 CFR Part 1610	Flammability of Clothing Textiles	Passed
ISO10993-1	Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing Within A Risk Management Process	Met the requirements
ISO10993-5	Biological Evaluation of Medical Devices - Part 5: Tests for In Vitro Cytotoxicity	No cyctotoxicity or cell lysis was noted.
ISO10993-10	Biological Evaluation of Medical Devices Part 10: Tests for Irritation and Sensitization, 1ed	No evidence of sensitization or irritation was observed.

Clinical Performance

No Clinical study is included in this submission. The device as designed does not posed any new or additional risks to user or patient.

Summary of Test Results:

The conclusions drawn from the nonclinical tests demonstrate that the devices are as safe, as effective, and perform as well as or better than the legally marketed device identified as the predicate device, K160269.