September 16, 2022

San-M Package Co., Ltd.
% Takahiro Haruyama
President
Globizz Corporation
1411 W 190th St. Toyota Plaza #200
Gardena, California 90248

Re: K221534
Trade/Device Name: Surgical Face Masks (Ear Loops And Tie-On)
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: May 24, 2022
Received: May 27, 2022

Dear Takahiro Haruyama:

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)*
K221534

Device Name
Surgical Face Masks (Ear Loops and Tie-On)

Indications for Use *(Describe)*

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. This mask is safe for use in the MR environment.

Level 1 Face Mask Models: # EL 10000, EL 10010, TO 10000, TO10010
Level 2 Face Mask Models: # EL 20000, EL 20010, TO 20000, TO 20010
Level 3 Face Mask Models: # EL 30000, EL 30010, TO 30000, TO 30010

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 for Surgical Face Masks (Ear loops and Tie-on)

1. Submission Sponsor

SAN-M PACKAGE CO., LTD.
1086-1 Ojiro
Shimada-City Sizuoka, Japan 428-8652

2. Submission Correspondent

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Title : President, Globizz Corporation
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Phone : (310) 538-3860
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3. Date Prepared

Aug 11th, 2022

4. Device Identification

Type of 510(k) :	Traditional 510(k)
Trade Name :	Surgical Face Masks (Ear loops and Tie-on)
Product Code :	FXX
Classification Name:	Surgical Mask
Regulation Number :	21 CFR §878.4040
Device Class:	Class II
Review Panel :	General & Plastic Surgery

5. Legally Marketed Predicate Device

Trade Name:	Surgical Face Masks (Ear loops and Tie-on)
510(k) Number:	K160269
Manufacturer:	SAN-M PACKAGE CO., LTD.

6. Indication for Use

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. This mask is safe for use in the MR environment.

Level 1 Face Mask Models: # EL 10000, EL 10010, TO 10000, TO10010
Level 2 Face Mask Models: # EL 20000, EL 20010, TO 20000, TO 20010
Level 3 Face Mask Models: # EL 30000, EL 30010, TO 30000, TO 30010

7. Device Description

The Surgical Face Masks (Ear Loops and Tie-On) are four-layer, flat-folded masks constructed of nonwoven polypropylene materials. The mask is provided with ear loops (polyester and polyurethane) or ties (polypropylene/polyester). A malleable nosepiece is placed within the binding for comfort and individualized fit. The surgical face masks will be provided in white and blue, and options for added cup keeper (polypropylene), visor (polyester), or both. The surgical face masks are single-use, disposable devices, provided non-sterile. This mask is safe for use in the MR environment.

8. Model Numbers

Table 1. Surgical Face Mask Model Comparison Table

Mask Feature	Subject Device	Predicate Device(K160269)
Mask Style	Ear Loops	Ear Loops
Level 1	EL 10000	EL 10000
Level 1 with Visor	EL 10010	EL 10010
Level 2	EL 20000	EL 20000
Level 2 with Visor	EL 20010	EL 20010
Level 3	EL 30000	EL 30000
Level 3 with Visor	EL 30010	EL 30010
Mask Style	Tie-On	Tie-On

Level 1	TO 10000	TO 10000
Level 1 with Visor	TO 10010	TO 10010
Level 2	TO 20000	TO 20000
Level 2 with Visor	TO 20010	TO 20010
Level 3	TO 30000	TO 30000
Level 3 with Visor	TO 30010	TO 30010

9. Technological Characteristics

The subject device, Surgical Face Masks (Ear Loops And Tie-On) is substantially equivalent to the legally marketed predicate device, K160269 Surgical Face Masks (Ear Loops And Tie-On). There is one major difference between these devices, which is the material of the nose clamp from polyethylene coated steel wire to just polyethylene which allows for use in MRI environments.

10. Substantial Equivalence Discussion

Table 2: Comparison of Predicate and Subject Device, Surgical Face Masks (Ear Loops and Tie-On).

Feature	Subject Device			Predicate Device (160269)			Comparison
	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3	
Product Name	(New) Surgical Face Masks (Ear Loops And Tie-On)			(Our approved product) Surgical Face Masks (Ear loops And Tie-On)			Surgical Face Masks (Ear Loops and Tie-On) is San-M's previously approved

			product under K160269.
510(k) Clearance	--	K160269	--
Manufacturer	San-M Package Co., Ltd.	San-M Package Co., Ltd.	Equivalent.
Common Name	Surgical Mask	Surgical Mask	Equivalent.
Classification	Class II	Class II	Equivalent.
Product Code	FXX	FXX	Equivalent.
Intended Use	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 the potential exposure to blood and body fluids. This is a single-use, disposable device, provided non-sterile. This mask is safe for use in the MR environment.	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 the potential exposure to blood and body fluids. This is a single-use, disposable device, provided non-sterile.	Additional function of MR safe. Rest is equivalent.
Materials			
Outer Material	Polypropylene	Polypropylene	Equivalent.
Inner Material	Polypropylene	Polypropylene	Equivalent.
Filter Media	1.Polypropylene 2.Polypropylene meltblown	1.Polypropylene 2.Polypropylene meltblown	Equivalent.
Nose Clamp	Polyethylene	Polyethylene coated steel wire	Different. Steel wire is removed from nose clamp. New

							material passed the biocompatibility tests. No differences in performance.
Ear Loops/Tie Tapes	Ear loops: Polyester, polyurethane Side tapes: Polyester spunbond (ear loops mask only) Tie tapes: Polypropylene spunbond or polyester spunbond			Ear loops: Polyester, polyurethane Side tapes: Polyester spunbond (ear loops mask only) Tie tapes: Polypropylene spunbond or polyester spunbond			Equivalent.
Design Features	•Colors: white or blue •Cup keeper option: polypropylene •Visor option: polyester			•Colors: white or blue •Cup keeper option: polypropylene •Visor option: polyester			Equivalent.
Specifications and Dimensions	Length: 175 ± 5mm Width: 90 ± 3mm	Length: 180 ± 5mm Width: 90 ± 3mm		Length: 175 ± 5mm Width: 90 ± 3mm	Length: 180 ± 5mm Width: 90 ± 3mm		Equivalent.
Mask Style	Flat-pleated			Flat-pleated			Equivalent.
Sterility	Non-sterile			Non-sterile			Equivalent.
Performance Testing (ASTM F2100-11)	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3	Equivalent.
Fluid Resistance	ASTM F1862			ASTM F1862			Equivalent.

Particulate Filtration Efficiency	ASTM F2299	ASTM F2299	Equivalent.
Bacterial Filtration Efficiency	ASTM F2101	ASTM F2101	Equivalent.
Differential Pressure	MIL-M36945C	MIL-M36945C	Equivalent.
Flammability	16 CFR 1610	16 CFR 1610	Equivalent.
Biocompatibility	ISO 10993	ISO 10993	Equivalent.

Performance Testing:

The San-M Surgical Masks have been tested according to ASTM F2101-11**.**

Table 3: Comparison of performance and biocompatibility testing

ASTM F2100-11	**Subject Device San-M Surgical Masks**			**K160269**			**Compari-son**
	Level 1	**Level 2**	**Level 3**	**Level 1**	**Level 2**	**Level 3**	
Fluid Resistance (ASTM F1862)	Pass at 80 mmHg	Pass at 120 mmHg	Pass at 160 mmHg	Pass at 80 mmHg	Pass at 120 mmHg	Pass at 160 mmHg	Equivalent
PFE (ASTM F2299): ≥ 98%	Pass at 99.6%	Pass at 99.6%	Pass at 99.6%	Pass at 99.6%	Pass at 99.6%	Pass at 99.6 %	Equivalent

BFE (ASTM F2101): ≥ 98%	Pass at >98%	Pass at >98%	Pass at >99.9 %	Pass at >98%	Pass at >98%	Pass at >99%	Equivalent
Δ P (MIL-M-36954C): <5.0 mm H_2O/cm^2	Pass at 2.0 mm H_2O/cm^2	Pass at 1.6 mm H_2O/cm^2	Pass at 2.5 mm H_2O/cm^2	Pass at 2.0 mm H_2O/cm^2	Pass at 1.6 mm H_2O/cm^2	Pass at 2.5 mm H_2O/cm^2	Equivalent
Flammability (16 CFR 1610): Class 1	Class 1			Class 1			Equivalent
Cytotoxicity . ISO 10993-5	Under the conditions of the study, the subject device was non-cytotoxic.			Under the conditions of the study, the subject device was non-cytotoxic.			Equivalent
Irritation ISO 10993-10	Under the conditions of the study, the subject device was non-irritating.			Under the conditions of the study, the subject device was non-irritating.			Equivalent
Sensitization ISO 10993-10	Under the conditions of the study, the subject device was non-sensitizing.			Under the conditions of the study, the subject device was non-sensitizing.			Equivalent

11. Substantial Equivalence Conclusion

The subject device, Surgical Face Masks (Ear Loops and Tie-On) is substantially equivalent to the legally marketed predicate device, K160269 Surgical Face Masks (Ear Loops And Tie-On). There is one major difference between these devices, which is the material of the nose clamp from polyethylene coated steel wire to just polyethylene which allows for use in MRI environments. Therefore, we believe this device is regulated under the same regulation as K160269 Surgical Face Masks (Ear Loops and Tie-On): 21 CFR 878.4040 (Class II, Product code FXX for Masks, Surgical). The conclusions drawn for the nonclinical tests demonstrate that the device is as safe, as effective, and performs as well as or better than the identified predicate device.