DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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September 6, 2016

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

Re: K160269
Trade/Device Name: Surgical Face Masks (Ear loops and Tie-on)
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: FXX
Dated: August 2, 2016
Received: August 4, 2016

Dear Mr. 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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160269

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

Level 1 Face Mask Models: # EL 10000, EL 10010, TO 10000, TO 10010
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.

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

510(k) Owner/ Applicant	SAN-M PACKAGE CO., LTD. 1086-1 Ojiro Shimada-City Sizuoka, JAPAN 428-8652
510(k) Number	K160269
US Correspondent	Takahiro Haruyama Globizz Corporation (310) 538-3860 register@globizz.net
Date Prepared	August 30, 2016
Trade Name	Surgical Face Masks (Ear loops and Tie-on)
Common Name	Surgical Mask
Classification Name	Masks, Surgical
Review Panel	General & Plastic Surgery
Product Code	FXX
Device Classification	Class II per 21 CFR §878.4040
Predicate Device	The Surgical Face Masks (Ear loops and Tie-on) are substantially equivalent to the Kimberly-Clark KC100 Mask (K110455) and KC200 and KC300 Face Masks (K111402). A comparison between the proposed and predicate devices is shown in Table 5-A below.

Table 5-A. Comparison of characteristics.

Feature	**(Proposed Device) Surgical Face Masks (Ear loops and Tie-on)**			**(Predicate Device) KC100 Mask**	**(Predicate Device)**	
					KC200 Face Mask	**KC300 Face Mask**
	Level 1	**Level 2**	**Level 3**	**Level 1**	**Level 2**	**Level 3**
510(k) #	K160269			K110455	K111402	
Manufacturer	San-M Package Co., Ltd.			Kimberly-Clark	Kimberly-Clark	
Common Name	Surgical Mask			Surgical Mask	Surgical Mask	

Classification	Class II	Class II	Class II	
Product Code	FXX	FXX	FXX	
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.	The Kimberly-Clark KC100 Procedure Mask(s) 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 the potential exposure of the wearer to blood and body fluids. The Kimberly-Clark KC100 Procedure Mask(s) is a single use, disposable devices, provided non-sterile.	The Kimberly-Clark, KC200 and KC300 Face Mask(s) 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 the potential exposure of the wearer to blood and body fluids. The Kimberly-Clark, KC200 and KC300 face mask(s) is a single use, disposable device(s), provided non-sterile.	
Materials				
Outer Material	Polypropylene	Polypropylene spunbond	Polyester cellulose	Polypropylene spunbond
Inner Material	Polypropylene	Polyethylene/ Polyester	Polyester cellulose	
Filter Media	1. Polypropylene spunbond 2. Polypropylene meltblown	1. Polypropy-lene meltblown	1. Polypropylene spunbond 2. Polypropylene meltblown	

Nose Clamp	Polyethylene coated steel wire			N/A	N/A	
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/lycra knitted Tie tapes: Polyester spunlace	Ear loops: Polyester/lycra knitted Tie tapes: Polyester spunlace	
Design Features	• Colors: white or blue • Visor option: polyester			• Colors: variety • Visor option	• Colors: variety • Visor option	
Specifications and Dimensions	Length: 90 ± 3 mm Width: 175 ± 5 mm	Length: 90 ± 3 mm Width: 180 ± 5 mm		Length: 102 ± 19 mm Width: 165 ± 19 mm	Length: 102 ± 19 mm Width: 165 ± 19 mm	
Mask Style	Flat-pleated			Flat-pleated	Flat-pleated	
Sterility	Non-sterile			Non-sterile	Non-sterile	
Performance Testing (ASTM F2100-11)	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3
Fluid Resistance	ASTM F1862			ASTM F1862	ASTM F1862	
Particulate Filtration Efficiency	ASTM F2299			ASTM F2299	ASTM F2299	
Bacterial Filtration Efficiency	ASTM F2101			ASTM F2101	ASTM F2101	
Differential Pressure	MIL-M36945C			MIL-M36945C	MIL-M36945C	
Flammability	16 CFR 1610			16 CFR 1610	16 CFR 1610	
Biocompat-ibility	ISO 10993			ISO 10993	ISO 10993	

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 or blue and with the option for a visor. The surgical face masks are single-use, disposable devices, provided non-sterile.

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.

Model Numbers

Table 5-B. Surgical Face Mask Model Numbers

Mask Style	Ear Loops	Tie-On
Level 1	EL 10000	TO 10000
Level 1 with Visor	EL 10010	TO 10010
Level 2	EL 20000	TO 20000
Level 2 with Visor	EL 20010	TO 20010
Level 3	EL 30000	TO 30000
Level 3 with Visor	EL 30010	TO 30010

Technological Characteristics

The Surgical Face Masks (Ear loops and Tie-on) are substantially equivalent to the current legally marketed predicated devices cleared in K110455 and K111402. The product conforms to the recognized standards ASTM F2100-11, ASTM F1862, ASTM F2101, and ISO 10993 in addition to the requirements stated in the Guidance for Industry and FDA Staff: *Surgical Masks-Premarket Notifications [510(k)] Submissions*, issued March 5, 2004.

Performance & Biocompatibility Testing

The Surgical Face Masks (Ear loops and Tie-on) have been tested according to the Guidance for Industry and FDA Staff: *Surgical Masks-Premarket Notifications [510(k)] Submissions*, issued March 5, 2004.

Performance & Biocompatibility Testing (continued)

Table 5-C. Comparison of performance and biocompatibility testing.

TEST	(Proposed Device) Surgical Face Masks (Ear loops and Tie-on)			(K110455) KC100 Mask	(K111402)	
					KC 200 Face Mask	KC 300 Face Mask
	Level 1	**Level 2**	**Level 3**	**Level 1**	**Level 2**	**Level 3**
ASTM F2100-11	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3
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
ASTM F2299	Pass at 99.6%	Pass at 99.6%	Pass at 99.7%	Pass at 98.4%	Pass at 98.4%	Pass at 98.4%
ASTM F2101	Pass at >98%	Pass at >98%	Pass at >99%	Pass at 99.7%	Pass at 99.7%	Pass at 99.7%
MIL-M36945C	Pass at 2.0 mmH_2O/cm^2	Pass at 1.6 mmH_2O/cm^2	Pass at 2.5 mmH_2O/cm^2	Pass at 3.0 mmH_2O/cm^2	Pass at 4.5 mmH_2O/cm^2	Pass at 3.2 mmH_2O/cm^2
16 CFR 1610	Class 1	Class 1	Class 1	Class 1	Class 1	Class 1
Cytotoxicity **ISO 10993-5**	Under the conditions of the study, the subject device was non-cytotoxic.			Under the conditions of the study, the device was non-cytotoxic.	Under the conditions of the study, the device was non-cytotoxic.	
Irritation **ISO 10993-10**	Under the conditions of the study, the subject device was non-irritating.			Under the conditions of the study, the device was non-irritating.	Under the conditions of the study, the device was non-irritating.	
Sensitization **ISO 10993-10**	Under the conditions of the study, the subject device was non-sensitizing.			Under the conditions of the study, the device was non-sensitizing.	Under the conditions of the study, the device was non-sensitizing.	

Conclusions

The product proposed under this premarket notification submission is similar in design, intended use, technological characteristics, and is composed of the same or similar components as the predicate device. The product proposed under this premarket notification submission has the same or similar performance characteristics and conform to the same or similar standards. Differences between the Surgical Face Masks (Ear loops and Tie-on) and predicate devices did not raise any new concerns regarding safety and effectiveness. The conclusions drawn from the non-clinical tests demonstrate that the device is substantially equivalent to the predicate devices K110455 and K111402.