DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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July 15, 2016

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

Re: K160271
Trade/Device Name: N95 Particulate Respirator and Surgical Mask, Models TN01-11 and TN01-12
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: MSH
Dated: June 10, 2016
Received: June 15, 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,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
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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)*
K160271

Device Name
N95 Particulate Respirator and Surgical Masks, Models TN01-11 and TN01-12

Indications for Use *(Describe)*
The N95 Particulate Respirator and Surgical Mask, Models TN01-11 and TN01-12 are single-use, disposable devices, provided non-sterile, and are intended to be worn by operating room personnel or other healthcare workers to protect both the patient and operating room personnel from the 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.

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510(k) Summary for N95 Particulate Respirator and Surgical Mask

510(k) Owner/ Applicant	SAN-M PACKAGE CO., LTD. 1086-1 Ojiro Shimada-City Sizuoka, JAPAN 428-8652
US Correspondent	Takahiro Haruyama Globizz Corporation (310) 538-3860 register@globizz.net
Date Prepared	July 15, 2016
Trade Name	N95 Particulate Respirator and Surgical Mask, Models TN01-11 and TN01-12
Common Name	N95 Surgical Respirator
Classification Name	Surgical apparel
Review Panel	General Hospital
Product Code	MSH
Device Classification	Class II per 21 CFR §878.4040
Predicate Device	The N95 Particulate Respirator and Surgical Mask, Models TN01-11 and TN01-12 are substantially equivalent to the Prestige Ameritech Pro Gear N95 Particulate Filter Respirator and Surgical Mask cleared in K102092. A comparison between the proposed and predicate device is shown in Table 5-A below.

Table 5-A. Comparison of characteristics.

Feature	N95 Particulate Respirator and Surgical Mask (Proposed Device)	Pro Gear N95 Particulate Filter Respirator and Surgical mask (Predicate Device)
510(k) #	K160271	K102092
Manufacturer	San-M Package Co., Ltd.	Prestige Ameritech
Common Name	N95 Surgical Respirator	N95 Surgical Respirator
Classification #	Class II	Class II
Product Code	MSH	MSH
Intended Use	The N95 Particulate Respirator and Surgical Mask, Models TN01-11	The Prestige Ameritech N95 Respirator and Surgical Mask

	and TN01-12 are single-use, non-sterile, disposable devices intended to be worn by operating room personnel or other healthcare workers to protect both the patient and operating room personnel from the transfer of microorganisms, body fluids, and particulate material.	RP88020 is a single use non-sterile disposable device 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.
Materials		
Outer Material	Polypropylene spunbond	Polypropylene spunbond
Inner Material	Polypropylene and polyethylene	Biocomponent nonwoven
Filter Media	Two layers of polypropylene meltblown	Two layers of polypropylene meltblown
Nose Clamp	Polyethylene coated steel wire	Malleable aluminum
Headband	Polyurethane, not made with natural rubber latex	Elastic not made with natural rubber latex
Design Features	Manufactured by ultrasonic bonding, composed of four layers of materials, trapezoid-shaped when flat-folded, pouched-shaped when worn, single-use, disposable respirator, and nose clamp to contour to the wearer.	Manufactured by ultrasonic bonding, composed of four layers of materials pouched and pleated to form the mask. Held on wearer with an elastic headband and contains a malleable aluminum nosepiece strip.
Specifications and Dimensions	• Colors: orange or white TN01-12 (Small): • Length: 205 ± 5 mm • Width: 75 ± 5 mm • Band length: 205 ± 5 mm TN01-11 (Medium): • Length: 240 ± 5 mm • Width: 75 ± 5 mm • Band length: 240 ± 5 mm	N/A
Mask Style	Flat-folded, Pouch	Pouch
Sterility	Non-sterile	Non-sterile
Performance Testing		
Fluid Resistance	Pass at 160 mmHg (ASTM F1862)	Pass at 160 mmHg (ASTM F1862)
Particulate Filtration Efficiency(PFE)	NIOSH Certification # TC 84A-3348 (includes TN01-11 & TN01-12)	NIOSH Certification # TC 84A-5216

Bacterial Filtration Efficiency(BFE)	NIOSH Certification # TC 84A-3348 (includes TN01-11 & TN01-12)	NIOSH Certification # TC 84A-5216
Differential Pressure (Δ P)	NIOSH Certification # TC 84A-3348 (includes TN01-11 & TN01-12)	NIOSH Certification # TC 84A-5216
Flammability	Class 1 (16 CFR 1610)	Class 1 (16 CFR 1610)
Biocompatibility	Under the conditions of the study, the device was non-cytotoxic, non-sensitizing, and non-irritating. (ISO 10993)	(ISO 10993)

Device Description

The N95 Particulate Respirator and Surgical Mask, Models #TN01-11 and #TN01-12 are NIOSH certified (TC 84A-3348), pouched-shaped respirators when worn. The flat-folded masks are composed of four layers of materials consisting of polypropylene and polyethylene (inner layer), polypropylene meltblown (two filter layers), and polypropylene spunbond (outer layer). The masks contain a conformable nose clamp enclosed in a binding tape welding the top edge to conform to the contours of the face. In addition, the masks contain an ultrasonically welded, polyurethane elastic headband not made with natural rubber latex, to secure the masks in place on the wearer. The masks are offered in orange or white.

Intended Use

The N95 Particulate Respirator and Surgical Mask, Models TN01-11 and TN01-12 are single-use, disposable devices, provided non-sterile and are intended to be worn by operating room personnel or other healthcare workers to protect both the patient and operating room personnel from the transfer of microorganisms, body fluids, and particulate material.

Model Numbers

TN01-11: N95 Particulate Respirator and Surgical Mask (Medium Size)
TN01-12: N95 Particulate Respirator and Surgical Mask (Small Size)

Technological Characteristics

The N95 Particulate Respirator and Surgical Mask is substantially equivalent to the current legally marketed, NIOSH-certified Pro Gear N95 Particulate Filter Respirator and Surgical Mask (K102092). The product was tested according to the recognized standards 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 Testing

The N95 Particulate Respirator and Surgical Mask, Models TN01-11 and TN01-12 have been tested according to the Guidance for Industry and FDA Staff: *Surgical Masks-Premarket Notifications [510(k)] Submissions*, issued March 5, 2004. Where applicable, NIOSH certification number is provided in lieu of performance testing data as noted in the guidance document:

Table 5-B. Conformance to performance testing requirements.

Criteria	N95 Particulate Respirator and Surgical Mask Standard Test Results
Fluid Resistance	Models TN01-11 and TN01-12 meet the requirements of ASTM F1862.
Particulate Filtration Efficiency	NIOSH Certification Number: TC 84A-3348 (Models TN01-11 and TN01-12)
Bacterial Filtration Efficiency	NIOSH Certification Number: TC 84A-3348 (Models TN01-11 and TN01-12)
Differential Pressure	NIOSH Certification Number: TC 84A-3348 (Models TN01-11 and TN01-12)
Flammability	Meets 16 CFR 1610 Standard for class 1 flammability.
Biocompatibility	Referenced ISO 10993-1 to determine standard tests required for surface devices with limited contact (≤ 24 hours), contacting intact skin.
Cytotoxicity	Under the conditions of the study, the subject device was non-cytotoxic. (ISO 10993-5)
Irritation	Under the conditions of the study, the subject device was non-irritating. (ISO 10993-10)
Sensitization	Under the conditions of the study, the subject device was non-sensitizing. (ISO 10993-10)

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 are both fluid resistant with the flammability of Class 1. Both products are NIOSH certified and the N95 Particulate Respirator and Surgical Mask, Models TN01-11 and TN01-12 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 device K102092.