April 4, 2018

Master & Frank Enterprise Co., Ltd
% Field Fu
Official Correspondent
Shenzhen Joyantech Consulting Co., Ltd
Room 1122, No.55 Shizhou Middle Road, Nanshan District
Shenzhen, gd755 Cn

Re: K172963
Trade/Device Name: Master-Frank N95 Particulate Respirator
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: MSH
Dated: March 5, 2018
Received: March 13, 2018

Dear Field Fu:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Geeta K. Pamidimukkala -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)*
K172963

Device Name
Master-Frank N95 Particulate Respirator

Indications for Use *(Describe)*
The N95 Particulate Respirator (MF01) is single-use, disposable device, 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K172963

510(k) Summary

1. Submission Sponsor

Applicant Name	Master & Frank Enterprise Co., Ltd
Address	Banhu Industrial District, Huang Jiang,Dong Guan City, Guang Dong Province, CHINA
Phone No.	+86-769-83361381
Fax No.	+86-769-83362026
Contact Person	Ms. Shuge Zhao
Email	zhaosg.dg@master-frank.cn
Date Prepared	04/03/2018

2. Submission correspondent

Name	Shenzhen Joyantech Consulting Co., Ltd
Address	Room 1122, No.55 Shizhou Middle Road, Nanshan District, Shenzhen, Guangdong, P.R.China
Post Code	518000
Phone No.	86-755-86069197
Contact Person	Mr. Field Fu; Ms. Jessie You
Email	Jessie@cefda.com; cefda13485@163.com

3. Device Identification

Trade / Proprietary Name	Master-Frank N95 Particulate respirator
Common / Usual Name	N95 Surgical Respirator
Classification Name	Surgical apparel
Classification Regulation	21 CFR 878.4040
Product Code	MSH
Classification Panel	General Hospital

4. Legally Marketed Predicate Devices

Trade Name	N95 Particulate Respirator and Surgical Mask
510(k) Number	K160271
Product Code	MSH
Manufacturer	San-M Package Co., Ltd.

5. Device Description

The N95 particulate respirator (Model MF-01) is NIOSH certified (TC-84A-7697), pouched-shaped respirators when worn. The flat-folded respirator is composed of four layers-inner layer, filter (2 layers) and outer layer. The four layers are combined via ultrasonically welded. The respirator also contains a nose-piece enclosed in a binding tape welding the top edge to conform to the contours of the face. The respirator contains straps to secure the respirator in place on the wearer. The respirator is offered in white. The respirator is provided non-sterile and for single use only.

6. Indications for Use Statement

The N95 Particulate Respirator (MF01) is single-use, disposable device, 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.

7. Substantial Equivalence Discussion

Item	Proposed Device: Master-Frank N95 Particulate respirator	Predicate Device: N95 Particulate Respirator and Surgical Mask	Comments
510 (k) number	K172963	K160271	None
Manufacturer	Master & Frank Enterprise Co., Ltd	SAN-M PACKAGE CO., LTD.	None
Common name	N95 Surgical Respirator	N95 Surgical Respirator	Same
Classification name	Surgical apparel	Surgical apparel	Same
Classification	II	II	Same
Product code	MSH	MSH	Same
Indications for use	OTC: The N95 Particulate Respirator (MF01) is single-use, disposable device, provided non-sterile, and are intended to be worn by operating room personnel or other healthcare workers to protect	OTC: 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	Same

	both the patient and operating room personnel from the transfer of microorganisms, body fluids, and particulate material.	healthcare workers to protect both the patient and operating room personnel from the transfer of microorganisms, body fluids, and particulate material.	
Materials			
Outer material	Polypropylene spunbond non-woven fabric	Polypropylene spunbond	Same
Inner material	Polypropylene spunbond non-woven fabric	Polypropylene and polyethylene	All of the materials are common fabric material for making a respirator. Safety of the materials has been proved by biocompatibility testing.
Filter media	Two layers of melt-blown polypropylene fabric	Two layers of polypropylene meltblown	Same

Nose-piece (Nose clamp)	Polyethylene + steel wire	Polyethylene coated steel wire	Same
Straps (Headband)	Synthetic rubber	Polyurethane, not made with natural rubber latex	The allergy reaction to rubber has been mentioned as a warning in the labeling, and safety of the materials has been proved by biocompatibility testing.
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-piece to contour to the wearer.	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.	Same

Specifications and dimensions	**MF-01** The upper side length of trapezoid: 98mm The bottom side length of trapezoid: 240mm Width: 90mm Straps: Length: 580mm Width: 5mm	➢ **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	Similar (Size of MF-01 is similar with Medium)
Mask style	Flat-folded, Pouch	Flat-folded, Pouch	Same
Sterility	Non-sterile	Non-sterile	Same
Biocompatibility	The biocompatibility testing items were determined in accordance with the FDA guidance "Use of International Standard ISO 10993-1" and ISO 10993-1, the product is surface device with limited contact (within 24 hours) and contacting intact skin: ➢ Cytotoxicity (ISO 10993-5): the	Referenced ISO 10993-1 to determine standard tests required for surface devices with limited contact (□ 24 hours), contacting intact skin: ➢ Cytotoxicity (ISO 10993-5): the device was non-cytotoxic; ➢ Irritation (ISO 10993-10): the device was non-irritating;	Same

	device was non-cytotoxic; ➢ Irritation (ISO 10993-10): the device was non-irritating; ➢ Sensitization (ISO 10993-10): the device was non-sensitizing.	➢ Sensitization (ISO 10993-10): the device was non-sensitizing.	
Performance testing			
Fluid resistance	Pass at 160 mmHg (ASTM F1862)	Pass at 160 mmHg (ASTM F1862)	Same
Flammability	Class 1 (16 CFR 1610)	Class 1 (16 CFR 1610)	Same
Particulate filtration efficiency (PFE)	NIOSH Certification # TC-84A-7697	NIOSH Certification #TC 84A-3348 (includes TN01-11 & TN01-12)	Same

Bacterial filtration efficiency (BFE)	NIOSH Certification # TC-84A-7697	NIOSH Certification #TC 84A-3348 (includes TN01-11 & TN01-12)	Same
Differential Pressure (Δ P)	NIOSH Certification # TC-84A-7697	NIOSH Certification #TC 84A-3348 (includes TN01-11 & TN01-12)	Same

8. Non-Clinical Performance Data

8.1 Biocompatibility testing

The N95 particulate respirators have been subjected to biocompatibility studies to demonstrate the safety of device. The biocompatibility studies are in accordance with ISO10993:

- In Vitro Cytotoxicity (ISO 10993-5): the device was non-cytotoxic;
- Skin Irritation (ISO 10993-10): the device was non-irritating;
- Skin Sensitization (ISO 10993-10): the device was non-sensitizing.

There is no additional safety risk for the products when compared with the predicate device (N95 Particulate Respirator and Surgical Mask).

8.2 Physical performance testing

The N95 particulate respirator (Model MF-01) is NIOSH certified (TC-84A-7697). The performance testing was determined from the guidance “Surgical Masks – Premarket Notification (510k) Submissions” to demonstrate the effectiveness of device:

- Fluid resistance:

Pass at 160 mmHg (ASTM F1862)

- Flammability:

  Class I (16 CFR 1610)

- NIOSH Certification # TC-84A-7697 to address the following:
  - Particulate filtration efficiency (PFE)
  - Bacterial filtration efficiency (BFE)
  - Differential Pressure (Δ P)

The N95 particulate respirator (Model MF-01) passed tests performed by NIOSH.

9. Conclusion

The Indications for Use, materials, design features, specifications and technological characteristics for N95 particulate respirators are similar to the predicate device (K160271). The non-clinical performance testing demonstrates that the Master-Frank N95 Particulate Respirator is as safe, as effective, and performs as well as the legally marketed predicate device (K160271).