2018/4/4

e-mail

U.S. FOOD & DRUG ADMINISTRATION

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

FDA

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 & HUMAN SERVICES

Centers for Disease Control and Prevention (CDC)
National Institute for Occupational Safety and Health (NIOSH)
National Personal Protective Technology Laboratory (NPPTL)
626 Cochrans Mill Road
Pittsburgh, PA 15236-0070
Phone: 412-386-4000
Fax: 412-386-4051

NIOSH Reference: TN-23893
Mfr. Reference: 171

June 10, 2020

Shuge Zhao
Master & Frank Enterprise Co. Ltd.
19F. No. 57, Sec. 2
Tun Hwa South Road
Taipei
TAIWAN

Dear Shuge Zhao:

The National Institute for Occupational Safety and Health (NIOSH) has reviewed your request accepted May 8, 2020. This request was for extension of approval TC-84A-7697 for an alternate filter media for the model MF-01 N95 air-purifying filtering facepiece respirator. The complete respirator configuration is detailed on assembly matrix file name *170AMa7.xls*, revision A7, dated: April 21, 2020.

This request is granted. Approvals are granted only for documentation written in the English language. It is the manufacturer's responsibility to correctly translate materials desired in languages other than English.

The approval label is included as an attachment to this letter. The cautions and limitations are listed on the approval label. Only those assemblies affected by this request, or where new approval numbers are assigned, apply to this approval action. Production approval labels cannot include information on unapproved configurations.

The approved assemblies consist of the parts as listed on the approval labels and the assembly matrix. Parts are to be marked with the numbers indicated on the approval labels in a legible and permanent manner (marking cannot be removed without evidence of its previous presence).

No changes may be made to any respirators and accompanying documentation without prior written approval of NIOSH. Requests for changes must be submitted to NIOSH and a modification of this approval must be granted before changes are made.

Additional note: This application informed NIOSH that respirator model MF-01 has been cleared by the U.S. Food and Drug Administration (FDA) as a surgical mask under 510(K) K172963, April 4, 2018.

Sincerely,

Jeffrey Peterson
Chief, Conformity Verification and
Standards Development Branch

Enclosures

National Institute for Occupational Safety and Health NIOSH®	**National Institute for Occupational Safety and Health** **National Personal Protective Technology Laboratory** **Evaluation and Testing Branch**

TEST REPORT

Task Number: TN-23893

Manufacturer: Master & Frank Enterprise Co., Ltd.

Prepared by: Jeremy Brannen

Date: May 29, 2020

Tests Conducted by: Jeremy Brannen

Respirator Tested: MF-01

Tests Completed

Test Description	STP Number
A. Exhalation Resistance Test	TEB-APR-STP-0003
B. Inhalation Resistance Test	TEB-APR-STP-0007
C. Sodium Chloride (NaCl) N95 Test	TEB-APR-STP-0059

Overall Results

The respirator system tested met the requirements of all the above procedures.

National Institute for Occupational Safety and Health
Respirator Branch
Test Data Sheet

Task Number: TN-23893 **Reference No.:** CFR 84.180
Test: Exhalation Resistance Test **STP No.:** 3
Manufacturer: Master & Frank Enterprise Co., Ltd.

Filter Type: Filter Only

Item Tested: MF-01

Sample	Maximum Allowable Resistance (MM of H2O) Exhalation	Actual Resistance (MM of H2O) Exhalation	Result
1	25	7.4	PASS
2	25	7.9	PASS
3	25	7.6	PASS

Overall Result: PASS

Comments:

Was all equipment verified to be in calibration throughout all testing? (•) Yes ( ) No

Signature: Jeremy Brannen **Date:** 5/29/2020

Engineering Technician

Task Number: TN-23893 **Reference No.:** CFR 84.180

Test: Exhalation Resistance Test **STP No.:** 3

Manufacturer: Master & Frank Enterprise Co., Ltd.

Signature:  **Date:** 5/29/2020

Engineering Technician

National Institute for Occupational Safety and Health
Respirator Branch
Test Data Sheet

Task Number: TN-23893
Test: Inhalation Resistance Test
Manufacturer: Master & Frank Enterprise Co., Ltd.
Item Tested: MF-01

Reference No.: CFR 84.180
STP No.: 7

Filter Type: Filter Only

Sample	Maximum Allowable Resistance (MM of H2O) Inhalation	Actual Resistance (MM of H2O) Inhalation	Result
1	35	8.1	PASS
2	35	7.9	PASS
3	35	8.1	PASS

Overall Result: PASS

Signature: 

Date: 5/29/2020

Engineering Technician

Task Number: TN-23893 **Reference No.:** CFR 84.180

Test: Inhalation Resistance Test **STP No.:** 7

Manufacturer: Master & Frank Enterprise Co., Ltd.

Item Tested: MF-01

Comments:

Was all equipment verified to be in calibration throughout all testing?	◉ **Yes**	○ **No**

Signature: 

Date: 5/29/2020

Engineering Technician

National Institute for Occupational Safety and Health
Evaluation and Testing Branch
Test Data Sheet

Task Number: TN-23893 **Reference No.:** CFR 84.181
Test: Sodium Chloride (NaCl) - N95 **STP No.:** 59
Manufacturer: Master & Frank Enterprise Co., Ltd.
Item Tested: MF-01

Filter	Flow Rate lpm	Initial Filter Resistance mm water gauge	Maximum Allowable Percent Leakage	Initial Percent Leakage	Maximum Percent Leakage	Result
1	85	8.7	5.00	0.549	0.566	PASS
2	85	9.1	5.00	0.671	0.671	PASS
3	85	7.8	5.00	0.565	0.575	PASS
4	85	7.3	5.00	0.328	0.539	PASS
5	85	9.0	5.00	0.741	0.741	PASS
6	85	8.7	5.00	0.745	0.745	PASS
7	85	8.7	5.00	0.765	0.774	PASS
8	85	9.7	5.00	0.745	0.745	PASS
9	85	10.1	5.00	0.924	0.924	PASS
10	85	8.1	5.00	0.815	0.820	PASS
11	85	9.3	5.00	0.718	0.718	PASS
12	85	9.7	5.00	0.775	0.775	PASS
13	85	9.2	5.00	0.727	0.727	PASS
14	85	9.7	5.00	0.694	0.694	PASS
15	85	9.3	5.00	0.647	0.652	PASS
16	85	9.0	5.00	0.725	0.728	PASS
17	85	8.7	5.00	0.674	0.674	PASS
18	85	9.3	5.00	0.829	0.829	PASS
19	85	9.3	5.00	0.681	0.681	PASS
20	85	9.1	5.00	0.778	0.778	PASS

Overall Result: PASS

Signature: 

Date: 5/29/2020

Engineering Technician

Task Number: TN-23893 **Reference No.:** CFR 84.181

Test: Sodium Chloride (NaCl) - N95 **STP No.:** 59

Manufacturer: Master & Frank Enterprise Co., Ltd.

Item Tested: MF-01

Comments:

Samples 1 and 2 were tested using the 000333TSI machine, samples 3 and 4 were tested using the 000388 TSI machine, and samples 5-20 were tested using the 000334 TSI machine.

Was all equipment verified to be in calibration throughout all testing?	◉ **Yes**	○ **No**

Signature: Jeremy Brammer **Date:** 5/29/2020

Engineering Technician

SINCE 1988

TEST REPORT

Test Report No: **RZ17010023**

Client: **Master & Frank Enterprise Co., Ltd**

Name of Samples: **N95 Particulate Respirator**

Model / Type: **MF-01**

Test Type: Certification (√)

Commission ( )

Others ( )

Guangzhou Medical Instruments Quality Surveillance and Inspection Center of State Food and Drug Administration

Notice

1. This test report is not valid without stamps of the test organization.
2. This test report is not allowed to be copied without written permission from the test organization.
3. Copies of this test report are not valid without stamps of the test organization.
4. This test report is not valid without the signature of the ratifier.
5. This test report is not valid with any alteration.
6. If any objection occurs, it should be submitted in written way to the test organization in 15 days from the day that this test report had been received.
7. This test report is only responsible for the test samples.

Testing Center: No.1 Guang pu west Lu, Science City of Luogang area in Guangzhou

020-66602380 020-66602381 020-66602382

020-66602383 020-66602384

Dong Guan Laboratory: Industry District, Zhang Village, Dong Guan

Shen Zhen Laboratory: No. 106,western,Fu An the mansion of science and technology, Nanshan,S&T park ,Shenzhen,Guangdong

0755-26010653

San Shui Laboratory: No 2,Southeast road, Industrial park of le ping, San Shui,fo Shan,Guangdong

0757-87652008 0757-87652011

Zhan Jiang Laboratory: No. 60 Shenchuan Avenue Middle, Xiashan District, Zhanjiang,Guangdong 0759-2836885

Zhong Shan Laboratory: 1st floor, No. 1 building, No. 8-4 Buyun Road, Torch Development Zone, Zhongshan, Guangdong Province

0760-85289967

Fax: 020-66602400

Website: www.gdmit.cn

E-mail: gdmitc-ywb@gdda.gov.cn

Guangzhou Medical Instruments Quality Surveillance and Inspection Center of State Food and Drug Administration

Test Report №:RZ17010023

Name of Samples	N95 Particulate Respirator Send-off (√) / Spot check (/)	Samples' Serial №	RZ17010023
Trademark	/	Model / Type	MF-01
Client	Master & Frank Enterprise Co., Ltd	Test Type	Certification
Client's Address	Banhu Industrial District, Huang Jiang, Dong Guan City, Guang Dong Province	Products'№ / Lot №	20170809
Manufacturer	Master & Frank Enterprise Co., Ltd	Sampling Bill №	——
Corporation being inspected	Master & Frank Enterprise Co., Ltd	Manufacturing date	2017.08.09
Sampled by	——	Samples' Quantity	18pcs
Sampling Place	——	Cardinal Number of Samples	——
Sampling Date	——	Test Place	Guangzhou Medical Devices Quality Surveillance and Test Center of CFDA
Receiving Date	2017/08 /30	Test Date	2017/08 /31～2017 /09/08
Test Items	Test for resistance of surgical mask to penetration by synthetic blood		
Test According to	ASTM F 1862: Standard test method for resistance of surgical mask to penetration by synthetic blood (Horizontal projection of fixed volume at a known velocity) GB 19083-2010: Technical requirements for protective face mask for medical use YY/T 0691-2008: Clothing for protection against infectious agents - Medical face masks - Test method for resistance against penetration by synthetic blood (fixed volume, horizontally projected)		
Test Conclusion	N95 particulate respirators were tested on a pass basis at 635cm/s velocity corresponding to human blood pressure at 160 mmHg. (Stamps of Test Organization) Issued Date: 二〇一七年九月十二日		
Remarks	In this test report, ——means the item is not applicable, and / means the item is blank.		
Signature	Tested by: LiuZhongyou, ZhengYangyu 刘忠友 郑仰煜 Reviewed by: HuangMinju Approved by (Authorized Signatory):		

1. Objective: This test is used to evaluate the resistance of N95 particulate respirators to penetration by the impact of a small volume (2mL) of a high velocity stream of synthetic blood by 10.6kPa,16.0kPa and 21.3kPa （I. e. 80mmHg，120mmHg and160mmHg）respectively. Medical face mask pass/fail determinations are based on visual detection of synthetic blood penetration.

2. Apparatus and Reagents

2.1 Apparatus

1) Test apparatus: consists of a specimen holding fixture, a targeting plate, a pressurized fluid reservoir, a pneumatically actuated valve with interchangeable canula and a valve controller;

2) Air pressure source;

3)Balance with a precision of at least 0.01 grams;

4)Breaker or cup with a precision of at least 0.1mL;

5) Temperature/Humidity recorder;

6) Controlled temperature and humidity chamber;

2.2 Reagents

1) Synthetic blood: prepare as the following steps:

a) Using the following ingredients to prepare: High Performance Liquid Chromatography (HPLC), quality distilled water (1.0L, pH 6.80), thickening agent 25.0g, and red dye 10.0g;

b)Boil the distilled water for 5min and allow to cool to room temperature before mixing. Measure amount of distilled water at 20℃ after boiling; Add the thickening agent to the distilled water and mix 45 min at room temperature on a magnetic stirring plate; Add the red dye and re-mix 15 min;

c)Only the synthetic blood with corrected surface tension is 0.043N/m used in this test; the synthetic blood was determined within the range, so it could be used in this test;

d) If the corrected surface tension is too low, remove excess surfactant from the red dye by mixing 25g of red dye with 1L of 90% isopropanol, decant 80% of the tainted alcohol, and discard or save for distillation; pour dye-alcohol solution into an evaporation dish, spread thin, and cover with filter paper to allow residual alcohol to completely evaporate. The red dye is ready for use when dry.

e) Remove excess surfactant from the synthetic blood by allowing the mixture to settle for 24h and then by carefully decanting the top 10% of the mixture;

f) Store synthetic blood in a plastic or glass container at room temperature;

g) Ensure that the synthetic blood is thoroughly mixed before using;

h) Discard the solution if a gel-like precipitate forms.

2) Isopropanol: laboratory grade.

3. Specimens: There were 18pcs N95 particulate respirators to be used for the test, which were divided into 3 groups on average; each group was corresponding to one stream velocity.

4.Preconditioning of specimen masks: 85% relative humidity at 24℃, for 4h; The specimen mask should be tested within 1min after it was taken out from controlled temperature and humidity chamber.

5. Test methods

5.1 Preparation and cleaning of test apparatus

a) Installed a clean canula on the front of the pneumatic-controlled valve;

b) Filled the reservoir with fresh synthetic blood (approximately 1L);

c) Adjusted the valve time to deliver 2mL of test fluid to the mask through the targeting plate;

d) For standard synthetic blood, the timer durations were adjusted as the following table:

Pressure/kPa	Velocity/（cm/s）	Valve time and timer duration/s
10.6	450	0.80
16.0	550	0.66
21.3	635	0.57

e) Verified each valve time with each corresponding velocity can delivered 2mL of test fluid by using a cup to collect the test fluid and weight it;

f) After every sixteen specimens, ensured that the test apparatus is delivering 2mL of synthetic blood by collecting and weighting the output passing through the targeting hole;

g) If the canula has been left for 1h or more without use after passing synthetic blood during testing, replaced with a clean canula and cleaned the used canula;

h) Cleaned the canula by immersing in isopropanol for 24h and rinsed with distilled water;

i) Following testing, cleaned system lines and the reservoir with distilled water.

5.2 Procedure

a)All tests was performed in the environment with 82%～85% relative humidity at 23℃～25℃;

b) Placed a small droplet of the synthetic blood on the normal inside surface of an extra medical face mask, the droplet could be easily visible;

c) Divided the 18 specimen masks into 3 groups on average, each group was corresponding with one pressure;

d)Mounted a specimen mask on the specimen holding fixture and position the specimen so the impact of the synthetic blood occurs in the desired area of the mask; located the exit of the canula 305mm from the target area of the specimen mask;

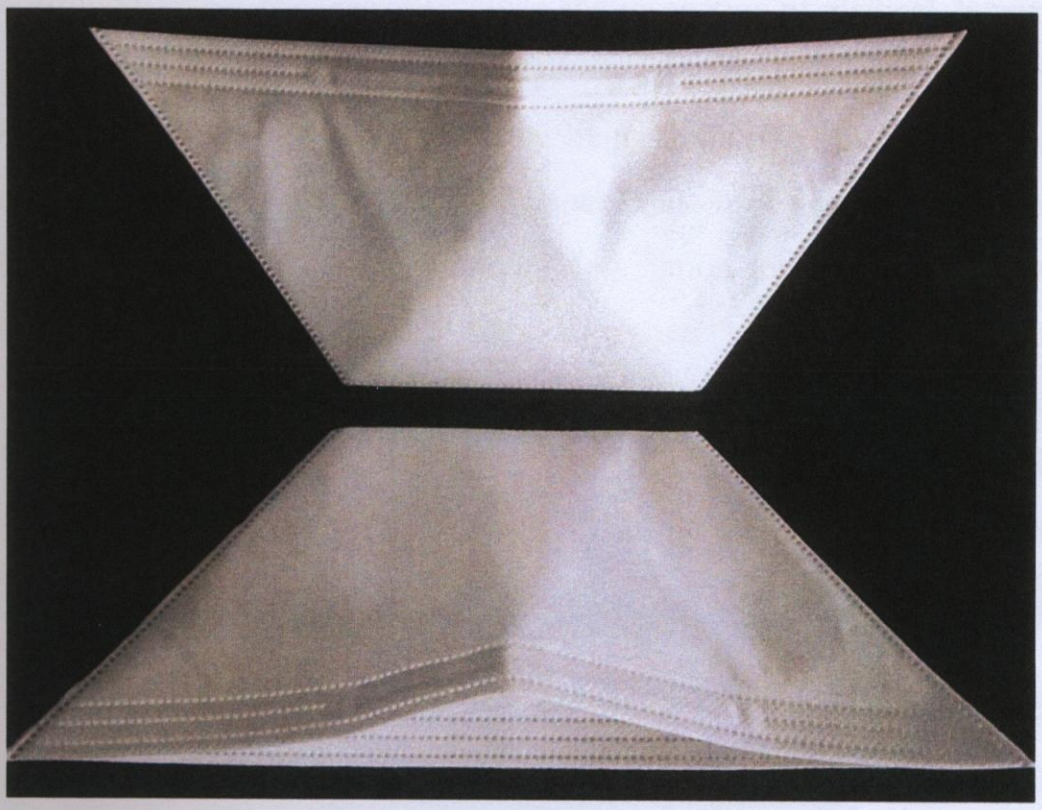
e) Dispensed the synthetic blood onto the specimen mask within 1min after it was taken out from controlled temperature and humidity chamber;

f) Inspect the viewing side of the specimen for synthetic blood within 10s of dispensing the synthetic blood against the target area;

g) Test the remaining specimens at each of the pressures.

6. Results

Specimen No.	Pressure	Results(penetration/no penetration)	Each test judgement (pass/fail)
1	10.6kPa（80mmHg）	no penetration	pass
2	10.6kPa（80mmHg）	no penetration	pass
3	10.6kPa（80mmHg）	no penetration	pass
4	10.6kPa（80mmHg）	no penetration	pass
5	10.6kPa（80mmHg）	no penetration	pass
6	10.6kPa（80mmHg）	no penetration	pass
7	16.0kPa（120mmHg）	no penetration	pass
8	16.0kPa（120mmHg）	no penetration	pass
9	16.0kPa（120mmHg）	no penetration	pass
10	16.0kPa（120mmHg）	no penetration	pass
11	16.0kPa（120mmHg）	no penetration	pass
12	16.0kPa（120mmHg）	no penetration	pass
13	21.3kPa（160mmHg）	no penetration	pass
14	21.3kPa（160mmHg）	no penetration	pass
15	21.3kPa（160mmHg）	no penetration	pass
16	21.3kPa（160mmHg）	no penetration	pass
17	21.3kPa（160mmHg）	no penetration	pass
18	21.3kPa（160mmHg）	no penetration	pass

Photos and Explanations

Samples' Descriptions
/
Types and Specifications or Other Explanations
/

广州医疗器械质量监督检验中心 检验检测专用章

STATEMENT

Guangzhou Medical Devices Quality Surveillance and Test Institute is a third-party inspection and test institution as an independent legal entity in full responsibility. The institution also serves as Guangzhou center of China Food and Drug Administration for the surveillance and inspection of medical devices quality, the inspection and test center of Guangdong Food and Drug Administration for packaging material and container, while being authorized by the government as Guangdong station for quality surveillance and inspection of drug packaging material and products as well as Guangdong station for quality surveillance and inspection of medical devices. The aforementioned "two centers and two stations" are under the same administration of Guangzhou Medical Devices Quality Surveillance and Test Institute, sharing the same leadership, organizational structure, personnel, and laboratory equipments, providing responsible data in the form of test reports for the public under the commission from authorities and clients.