LHM
Past Present Future

立興醫療科技（香港）有限公司
LHM Medical Technology (Hong Kong) Limited

Dated 27th February 2021

Announcement

Dear valued customer,

We are proud to announce that we have obtained the approval of Section 510(k) premarket notification on class II medical device from the Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) on 25th February 2021. Please refer to the attached file for your perusal.

Thus far, "LHM" is the first and only mask manufacturing company in Hong Kong which is qualified for supplying Class II medical device, among 281 companies globally.

We truly thank each healthcare professionals and organizations for continued support. Also, we commit to continually provide the highest quality of products and services for use in healthcare environment in future.

公告

致各位醫護專業客戶：

本公司於2021年2月25日接獲美國食品及藥物管理局通知，本公司之510K(二類醫療器材）申請已經成功批准上市，詳情請閱附件。

至今此為全球281家中，在香港唯一及首家申請獲得批核之二類醫療器械之口罩生產商。

在此感謝每位專業醫護人員及機構過去之支持，本公司承諾將在未來堅持為各專業人士提供優質產品及服務。

For and on behalf of LHM Medical Technology (Hong Kong) Limited

Pauline Wong
Executive Director

Unit 2, 3/F Block A, Ko Fai Industrial Building, 7 Ko Fai Road, Yau Tong, Kowloon, Hong Kong
香港九龍油塘高輝道 7 號高輝工業大廈 3 樓 A2 室

February 25, 2021

LHM Medical Technology (Hong Kong) Limited
Frank Cheng
Senior Manager of Quality Control
Unit No. 2, 3/F., Block A, Ko Fai Industrial Building,
7 Ko Fai Road,Yau Tong
HongKong, 999077
China

Re: K202240
Trade/Device Name: Disposable Surgical Mask/Fluid Resistant Procedure Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: February 6, 2021
Received: February 9, 2021

Dear Frank Cheng:

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,

Ryan Ortega -S

Ryan Ortega, PhD
Acting Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

510(k) Summary: K202240

I. Submitter

LHM Medical Technology (Hong Kong) Limited
Unit No. 2, 3/F., Block A, Ko Fai Industrial Building, No. 7 Ko Fai Road, Yau Tong, Kowloon, Hong Kong

Establishment Registration Number: 3016866341

Contact person: Frank Cheng
Position: Senior Manager of Quality Control
Tel.: +852-27558748- Ext1169
E-mail: frank.cheng@liphing.com

Preparation date: Feb.15, 2021

II. Proposed Device

Trade Name of Device:	Disposable Surgical Mask / Fluid Resistant Procedure Mask
Common name:	Surgical Mask
Regulation Number:	21 CFR 878.4040
Regulatory Class:	Class II
Product code:	FXX
Review Panel	General Hospital

III. Predicate Devices

510(k) Number:	K160269
Trade name:	Surgical Face masks (Ear loops and Tie-on)
Common name:	Surgical Mask
Classification:	Class II
Product Code:	FXX
Manufacturer	San-M Package Co., Ltd.

IV. Device Description

The Fluid Resistant Procedure Masks are Flat Pleated type mask, utilizing Ear Loops way for wearing, and they all have Nose Piece design for fitting the face mask around the nose. The Fluid Resistant Procedure Masks are manufactured with three layers.

The outer layer is made of spun-bond polypropylene non-woven fabric. The middle layer with filtration function is made of melt blown polypropylene non-woven fabric. The inner layer which contacts with face is made of spun-bond polypropylene non-woven fabric.
The Fluid Resistant Procedure Masks are single use, disposable device, provided non-sterile.

V. Indication for Use

The Fluid Resistant Procedure Masks are intended to be worn to protect the patient and healthcare personnel from transfer of microorganisms, blood 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.

VI. Comparison of Technological Characteristics with the Predicate Devices

Table 1 General Comparison

Item	Proposed Device (K202240)	Predicate Device (K160269)	Comparison
Trade Name	Disposable Surgical Mask/ Fluid Resistant Procedure Mask	Surgical Face masks (Ear loops and Tie-on)	-
Product Code	FXX	FXX	Same
Regulation No.	21 CFR 878.4040	21 CFR 878.4040	Same
Class	Class II	Class II	Same
Mask Style	Flat-pleated, ear loops, 3 layers	Flat-pleated, ear loops or tie-on, 4 layers	Different[2]
Indication for Use	The Fluid Resistant Procedure Masks are intended to be worn to protect the patient and healthcare personnel from transfer of microorganisms, blood fluids, and particulate material. These face masks are intended for use in infection control	The Surgical facemasks are intended to be worn to protect the patient and healthcare personnel from transfer of microorganisms, blood fluid, and particulate material. These face masks are intended for use in infection control practices to reduce the	Same

		practices to reduce the potential exposure to blood and body fluids. This is a single-use, disposable device, provided non-sterile.	potential exposure to blood and body fluid. This is a single-use, disposable devices provided non-sterile.		
Material	Inner layer	Spun-bond polypropylene	Polypropylene		Same
	Middle layer	Melt blown polypropylene filter	1. Polypropylene spun-bond 2. Polypropylene melt blown		Different[1]
	Outer layer	Spun-bond polypropylene	Polypropylene		Same
	Ear loops	88% Nylon + 12% Spandex	Ear loops: Polyester, polyurethane; Side tapes: Polyester spun-bond (ear loops mask only) Ties tapes: Polypropylene spun-bond or polyester spun-bond		Different[1]
	Nose piece	Iron wire covered by polypropylene	Polyethylene coated steel wire		Different[1]
Color		Blue	Blue ,white		Different[1]
Length		17.5cm	17.5cm	18.0cm	Different[2]
Width		9.5cm	9.0cm	9.0cm	
OTC Use		Yes	Yes		Same
Sterile		Non-sterile	Non-sterile		Same
Single for Use		Yes	Yes		Same
Fluid Resistance Performance ASTM F1862		Pass at 160mmHg	Level 1: Pass at 80mmHg Level 2: Pass at 120mmHg Level 3: Pass at 160mmHg		Different[2]

Particulate Filtration Efficiency ASTM F2299	>99.9% at 0.1μm	≥98.0%	
Bacterial Filtration Efficiency ASTM F2101	>99.9%	≥98%	
Differential Pressure	Average 3.52 mmH_2O/cm^2	Level 1: <5 mmH_2O/cm^2 Level 2&3: <6 mmH_2O/cm^2	
Flammability 16 CFR 1610	Class 1 Non Flammable	Class 1 Non Flammable	Same
In Vitro Cytotoxicity ISO 10993-5	Under the conditions of this study the device is non-cytotoxic	Under the conditions of this study the device is non-cytotoxic	Same
Skin Irritation ISO 10993-10	Under the conditions of this study the device is non-irritating	Under the conditions of this study the device is non-irritating	Same
Skin Sensitization ISO 10993-10	Under the conditions of this study the device is non-sensitizing	Under the conditions of this study the device is non-sensitizing	Same

Analysis:

[1] The differences in the materials and color do not raise additional questions for safety and effectiveness of the device. The biocompatibility evaluation tests of the subject devices have been performed on the final finished device which includes all construction materials and color additives. The test results show pass the requirements.

[2] The performances of proposed device have been performed the performance test according to method given in the ASTM F2100-19. The test results demonstrate that met the requirements in the standards. The minor difference between the proposed and predicate device does not affect the safety and effectiveness of the device.

VII. Summary of Non-Clinical Testing

Non-clinical performance tests were conducted to verify that the proposed device met all design specifications. The below table shows the test results of test article,

which demonstrated that the proposed device complies with the related standards. Each type of performance testing used 32 samples in each of 3 non-consecutive lots (totally 96 samples).

Table 2 Performance Testing

Methodology/ Standard	Purpose	Acceptance Criteria	Results
ASTM F1862M-17	Fluid Resistance Performance	29 out of 32 pass at 160mmHg	Pass (95/96)
ASTM F2299	Particulate Filtration Efficiency	≥98%	Pass (96/96) Average 99.9% at 0.1μm
ASTM F2101-19	Bacterial Filtration Efficiency	≥98%	Pass (96/96) Average 99.9%
EN 14683:2019 Annex C	Differential Pressure	<6mmH_2O/cm^2	Pass (96/96) Average 3.52 mmH_2O/cm^2
16 CFR 1610	Flammability	Class I Non Flammable	Pass (96/96) Meet Class I

The biocompatibility of the proposed device was tested in accordance with ISO 10993 and passed acceptance criteria.

Table 3 Biocompatibility Testing

Test Items	Standard	Result
Cytotoxicity	ISO 10993-5:2009, Biocompatibility Evaluation of Medical Device - Part 5: Tests for In Vitro Cytotoxicity	Under the conditions of the study, the subject device was non-cytotoxic.
Skin irritation	ISO 10993-10:2010, Biocompatibility Evaluation of Medical Device - Part 10: Tests for Irritation and Skin Sensitization	Under the conditions of the study, the subject device was non-irritating.
Skin Sensitization	ISO 10993-10:2010, Biocompatibility Evaluation of Medical Device - Part 10: Tests for Irritation and Skin Sensitization	Under the conditions of the study, the subject device was non-sensitizing.

VIII. Clinical Testing

No clinical study is included in this submission.

IX. Conclusion

The proposed device has the same indication for use and has similar design features and technological characteristic as the predicate device. Performance testing data demonstrates that the proposed device is as safe, as effective and performs as well as the legally marketed predicate device.