



July 30, 2021

Fujian MEO Medical Technology Limited  
% Boyle Wang  
General Manager  
Shanghai Truthful Information Technology Co., Ltd.  
Room 608, No. 738, Shangcheng Rd., Pudong  
Shanghai, Shanghai 200120  
China

Re: K210870

Trade/Device Name: MEO Med Disposable Medical Face Mask  
Regulation Number: 21 CFR 878.4040  
Regulation Name: Surgical Apparel  
Regulatory Class: Class II  
Product Code: FXX,  
Dated: June 16, 2021  
Received: June 23, 2021

Dear Boyle Wang:

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Clarence W. Murray, III, PhD  
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

## Indications for Use

510(k) Number (if known)  
K210870

Device Name  
MEO Med Disposable Medical Face Mask

### Indications for Use (Describe)

MEO Med Disposable Medical Face Mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. It is intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This is a single use, disposable device(s), provided non sterile.

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.

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## **510(k) Summary - K210870**

This summary of 510(k) is being submitted in accordance with requirements of SMDA 1990 and 21 CFR 807.92.

### **1.0 Submitter's information**

Name: Fujian MEO Medical Technology Ltd.  
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Business Development Zone, Ningde City, Fujian, 352100, CHINA  
Phone Number: +86-13599192517  
Contact: Ms. Zhuang Yan  
Date of Preparation: 16/03/2021

### **Designated Submission Correspondent**

Mr. Boyle Wang  
Shanghai Truthful Information Technology Co., Ltd.  
Room 608, No. 738 Shangcheng Rd., Pudong Shanghai, 200120 China  
Tel: +86-21-50313932  
Email: Info@truthful.com.cn

### **2.0 Device information**

Trade name: MEO Med Disposable Medical Face Mask  
Common name: MEO Med Disposable Medical Face Mask  
Classification name: Mask, Surgical  
Model(s): ear strap, 175×95mm

### **3.0 Classification**

Production code: FXX  
Regulation number: 21CFR 878.4040  
Classification: Class II  
Panel: Surgical apparel

### **4.0 Predicate device information**

Manufacturer: Wuhan Dymex Healthcare Co., Ltd  
Device: Surgical Face Mask  
510(k) number: K182515

### **5.0 Indication for Use Statement**

MEO Med Disposable Medical Face Mask is intended to be worn to protect both the

patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. It is intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This is a single use, disposable device(s), provided non sterile.

## **6.0 Device description**

The MEO Med Disposable Medical Face Mask is single use, three-layer, flat-pleated style with ear straps and nose piece. The mask is manufactured with three layers, the inner and outer layers are made of nonwoven fabrics, and the middle layer is made of melt blown fabrics. The ear straps are held in place over the users' mouth and nose by two elastic ear straps welded to the facemask. The elastic ear straps are not made with natural rubber latex. The nose piece on the layers of facemask is to allow the user to fit the facemask around their nose, which is made of HDPE (high density polyethylene). The MEO Med Disposable Medical Face Mask will be provided in blue. The masks are sold non-sterile and are intended to be single use, disposable devices.

## **7.0 Technological Characteristic Comparison Table**

**Table 1 - General Comparison**

<b>Item</b>	<b>Proposed device</b>	<b>Predicated device</b>	<b>Remark</b>
Product Code	FXX	FXX	Same
Regulation No.	21 CFR 878.4040	21 CFR 878.4040	Same
Class	II	II	Same
Product name	MEO Med Disposable Medical Face Mask	Surgical Face Mask	-
510(k) No.	K210870	K182515	-
Models	ear strap, 175×95mm	ear strap	-
Intended Use	The MEO Med Disposable Medical Face Mask is intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. It is intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This is a single use, disposable device(s), provided non sterile.	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(s), provided non-sterile.	Same
OTC use	Yes	Yes	Same
Composite	Flat Pleated, 3 layers	Flat Pleated, 3 layers	Same

Material	Internal layer	Spun-bond polypropylene	Spun-bond polypropylene	Same
	Middle layer	Melt blown polypropylene	Melt blown polypropylene	Same
	External layer	Spun-bond polypropylene	Spun-bond polypropylene	Same
	Nose piece	High Density Polyethylene	Malleable polyethylene wire	* Gap 1
	ear strap	Polyester, spandex	spandex	* Gap 2
Color		Blue	Yellow	* Gap 3
Dimension (Length)		17.5cm±0.5cm	17.5cm±0.2cm	* Gap 4
Dimension (Width)		9.5cm±0.5cm	9.5cm±0.2cm	* Gap 5
Sterility		Non-Sterile	Non-Sterile	Same
Single Use		Yes	Yes	Same
Sterile		No	No	Same
ASTM F2100 Level		Level 2	Level 2	Same

\* Gap analysis:

Gap 1-3: the two devices have some difference in materials and product colors, product materials safety is proved by its biocompatibility.

Gap 4-5: the two devices share same dimensions.

## **8.0 Non-Clinical Test Conclusion**

The proposed device was tested and conformed to the related recognized standards and the requirements stated in the Guidance for Industry and FDA Staff: MEO Med Disposable Medical Face Masks – Premarket Notification [510(k)] Submission issued on March 5, 2004.

**Table 2 - Performance Testing**

Test Methodology	Purpose	Acceptance Criteria (Level 2, ASTM F2100-19)	Result
Bacterial filtration efficiency (BFE) (%)	To measure the bacterial filtration efficiency (BFE) of medical face mask materials	≥98	Lot 1: 99.1%-99.9% passed Lot 2: 99.0%-99.9% passed Lot 3: 99.1%-99.9% passed  Pass
Different pressure (mmH <sub>2</sub> O/cm <sup>2</sup> )	To determine the breathability of medical face mask	<6.0 mmH <sub>2</sub> O/cm <sup>2</sup>	Lot 1: 3.9-4.9 mmH <sub>2</sub> O/cm <sup>2</sup> Passed  Lot 2: 4.0-4.9 mmH <sub>2</sub> O/cm <sup>2</sup> Passed

			Lot 3: 3.8-4.8 mmH <sub>2</sub> O/cm <sup>2</sup> Passed  Pass
Sub-micron particulate filtration efficiency at 0.1 micron, % (PFE)	To measure the initial filtration efficiency of materials used in medical face masks	≥98	Lot 1: 99.29%-99.64% Passed  Lot 2: 99.31%-99.66% passed  Lot 3: 99.28%-99.68% passed  Pass
Resistance to penetration by synthetic blood, Minimum pressure in mmHg for pass result	To evaluate the resistance of medical face mask to synthetic blood penetration	29 of 32 test articles passed at 120mmHg	Lot 1: 309/315 passed Lot 2: 308/315 passed Lot 3: 308/315 passed  Pass
Flame spread	To measure the response of materials, products or assemblies to heat and flame.	Class 1	Lot 1: 315/315 passed Lot 2: 315/315 passed Lot 3: 315/315 passed  Pass

**Table 2 - Biocompatibility Testing**

Item	Proposed Device	Result
Cytotoxicity	Under the conditions of the study, the device is noncytotoxic.	Pass
Irritation	Under the conditions of the study, the device is nonirritating.	Pass
Sensitization	Under the conditions of the study, the device is nonsensitizing	Pass

No clinical study implemented for the MEO Med Disposable Medical Face Mask.

## **8.0 Clinical Test Conclusion**

### **10.0 Conclusion**

The conclusions drawn from the non-clinical test demonstrate that the proposed device is as safe, as effective, and performs as well as the legally marketed predicated device.