December 16, 2021

Liberty Mask LLC
% Timothy Kania
Consultant
mdi Consultants
55 Northern Blvd, Suite 200
Great Neck, New York 11021

Re: K211378
Trade/Device Name: LM Surgical Mask Level 3, LM Surgical Mask Level 2
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: May 3, 2021
Received: May 4, 2021

Dear Timothy Kania:

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,

For Clarence W. Murray, III, Ph.D.
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K211378

Device Name
LM Surgical Mask Level 2
LM Surgical Mask Level 3

Indications for Use *(Describe)*
The following Liberty 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 masks are intended for use in infection control practices to reduce the potential exposure to blood and body fluids.

These are single use, disposable device(s) provided non-sterile.

LM Surgical Mask Level 3, Model #: LM0787
LM Surgical Mask Level 2, Model #: LM0786

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.***

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# 510(k) SUMMARY

The assigned 510(k) number is: K211378

## 1. Submitter's Identification:


Manufacturer: Liberty Mask, LLC
Address: 1819 Firman Drive, Suite 101
Plano, Texas 75081

Contact: Mr. Will Kincaid
Title: Operations Manager
Phone Number: 214-915-2133
Email: willk@Libertymask.com


Date Summary Prepared: April 15, 2021


Official Correspondent: Mr. Tim Kania
mdi Consultants, Inc.
Phone Number: (732)-796-4565
Email: tim@mdiconsultants.com


## 2. Name of the Device:

Device Name(s): LM Surgical Mask Level 3, LM Surgical Mask Level 2
Model Number: LM0787, LM0786

Common Name: Surgical Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX

## 3. Information for the 510(k) Cleared Device (Predicate Device):

**Predicate Device:**
Disposable Surgical Face Mask Ear Loop and Tie-On
K153496
Xiantao Rayxin Medical Products

## 4. Device Description:

The LM Surgical Masks are white, single use, three-layer, pleated masks that come in 2 models: LM Surgical Mask Level 3 & LM Surgical Mask Level 2. The inner and outer layers are made of spun-bond polypropylene, and the middle layer is made of melt blown polypropylene. The masks are held in place over the users' mouth and nose by either two elastic ear loops, welded to the facemask.

The nose piece in the layers of facemask is to allow the user to fit the facemask around their nose. The nose piece is made of polypropylene coated steel wire.
The surgical face masks are sold non-sterile and are intended to be single use, disposable devices.

Two models will be sold:

LM Surgical Mask Level 3, Model #: LM0787
LM Surgical Mask Level 2, Model #: LM0786

The models are identical except for labeling.

## 5. Indications for Use:

The following Liberty 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 masks are intended for use in infection control practices to reduce the potential exposure to blood and body fluids.

These are single use, disposable device(s) provided non-sterile.

LM Surgical Mask Level 3, Model #: LM0787
LM Surgical Mask Level 2, Model #: LM0786

## 6. Comparison to the 510(k) Cleared Devices (Predicate Devices):

**Table 2**: Comparison to Predicate Device

| Device | Proposed device | Predicate device | Result |
|---|---|---|---|
| 510(k) Holder | Liberty Mask, LLC | Xiantao Rayxin Medical Products | -- |
| 510(k) Number | K211378 | K153496 | -- |
| Name | LM Surgical Mask Level 2<br>Model #: LM0786<br><br>LM Surgical Mask Level 3<br>Model #: LM0787 | Disposable Surgical Face Mask<br>Ear Loop and Tie-On | -- |
| Classification | Class II Device, FXX (21 CFR 878.4040) | Class II Device, FXX (21 CFR 878.4040) | Same |
| Intended use | The following Liberty 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 masks are intended for use in infection control practices to reduce the potential exposure to blood and body fluids.<br><br>These are single use, disposable device(s) provided non-sterile.<br><br>LM Surgical Mask Level 2 | The Disposable 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 |

| | | | |
|---|---|---|---|
| | Model #: LM0786<br><br>LM Surgical Mask Level 3<br>Model #: LM0787 | | |
| Mask style | Flat- Pleated | Flat - Pleated | Same |
| Design | Ear loop | Ear loop, Tie-On | Same |
| Layers | Three | Three | Same |
| Color | White<br>Standridge White 20790<br>CAS#13463-67-7 | Blue | Different but mitigated through biocompatibility testing |
| Target population | Adults | Adults | Same |
| Dimension (Length) | 17.0 cm +/- 4mm | 17.5 cm | Different |
| Dimension (Width) | 9.0 cm +/- 4mm | 9.5 cm | |
| Sterility | Non-sterile | Non-sterile | Same |
| Use | Single use, disposable | Single use, disposable | Same |
| Anatomical site | Nose and mouth | Nose and mouth | Same |
| Environment of use | OTC | OTC | Same |
| Material | | | |
| Outer facing layer | Spun bond Polypropylene | Spun bond Polypropylene | Same |
| Middle layer | Melt blown polypropylene Filter | Melt blown polypropylene Filter | Same |
| Inner facing layer | Spun bond Polypropylene | Spun bond Polypropylene | Same |
| Ear Loops | Spandex Elastic Cord. (Polyurethane terephthalate/nylon cover) | Polyester | Different but mitigated through biocompatibility testing |
| Nose piece | Polypropylene Coated Steel Wire | Malleable aluminum wire | Different but mitigated through biocompati |

| | | | | |
|---|---|---|---|---|
| | | | | bility testing |
| ASTM F2100 Level | Level 2 & 3 | Level 2 | | Different. No new issues of safety or effectiveness and higher protection provided by Proposed Device |
| Performance Testing Results | | | | |
| Performance tests | Subject device | Predicate device | Acceptance Criteria | Result |
| Fluid Resistance Performance ASTM F1862 | LM Surgical Mask Level 3, LM0787: 95 out of 96 samples passed from 3 nonconsecutive lots at 160mm Hg<br><br>LM Surgical Mask Level 2, LM0786: 96 out of 96 samples passed from 3 nonconsecutive lots at 160mm Hg | 32 out of 32 Pass at<br><br>160mm Hg | 29 out of 32 pass at 160mmHg | Similar & Acceptable |
| Particulate Filtration Efficiency ASTM F2299 | LM Surgical Mask Level 3, LM0787: 96 out of 96 passed from 3 nonconsecutive lots at an average of 99.09%<br><br>LM Surgical Mask Level 2, LM0786: 96 out of 96 passed from 3 nonconsecutive lots at an average of 98.42% | 99.67% | ≥ 98% | Similar & Acceptable |
| Bacterial Filtration Efficiency ASTM F2101 | LM Surgical Mask Level 3, LM0787: 96 out of 96 passed from 3 nonconsecutive lots at an average of 99.60%<br><br>LM Surgical Mask Level 2, LM0786: 96 out of 96 passed from 3 nonconsecutive lots at an average of 99.59% | 99.95% | ≥ 98% | Similar & Acceptable |
| Differential Pressure (Delta-P)<br><br>MIL-M-36954C | LM Surgical Mask Level 3, LM0787: 4.80mm$H_2O/cm^2$<br><br>LM Surgical Mask Level 2, LM0786: 5.20mm$H_2O/cm^2$ | 5.62mm$H_2O/cm^2$ | <6.0mm$H_2O/cm^2$ | Similar & Acceptable |

| | | | | |
|---|---|---|---|---|
| Flammability class 16CFR 1610 | The test was performed in accordance with 16 CFR 1610 STANDARD FOR THE FLAMMABILITY OF CLOTHING TEXTILES to evaluate the flammability of the test sample. Class I<br><br>LM Surgical Mask Level 3, LM0787: 96 out of 96 passed from 3 nonconsecutive lots at Class 1<br><br>LM Surgical Mask Level 2, LM0786: 96 out of 96 passed from 3 nonconsecutive lots at Class 1 | Class 1 | Class 1 | Similar & Acceptable |
| Biocompatibility (limited contact (<24h) surface devices on intact skin) | | | | |
| Cytotoxicity | Under the conditions of the study, the proposed device extract was determined to be non-cytotoxic. | Under the conditions of the study, the predicate device extract was determined to be non-cytotoxic. | | Same |
| Irritation | Under the conditions of the study, the proposed device non-polar and polar extracts were determined to be non-irritating. | Under the conditions of the study, the predicate device non-polar and polar extracts were determined to be non-irritating. | | Same |
| Sensitization | Under the conditions of the study, the proposed device non-polar and polar extracts were determined to be non-sensitizing. | Under the conditions of the study, the predicate device non-polar and polar extracts were determined to be non-sensitizing. | | Same |

## 7. Summary of Non-Clinical Testing

| **Standard** | **Test Methodology** | **Purpose** | **Acceptance Criteria** | **Results** |
|---|---|---|---|---|
| Fluid Resistance Performance ASTM F1862 | An arterial spray is simulated by the testing laboratory by spraying synthetic blood at a pressure of 160mm Hg. The test articles are hen examined to determine if any blood penetration has occurred. | This test is performed to evaluate Personal Protective Equipment against fluid penetration. An arterial spray is simulated to test the PPE. | 29 out of 32 pass at 160mmHg | LM Surgical Mask Level 3, LM0787: 95 out of 96 samples passed from 3 nonconsecutive lots at 160mm Hg<br><br>LM Surgical Mask Level 2, LM0786: 96 out of 96 samples passed from 3 nonconsecutive lots at 160mm Hg |
| Particulate Filtration Efficiency ASTM F2299 | Monodispersed PSL are nebulized, dried and passed through the test | The PFE test is performed to evaluate the non-viable | ≥ 98% | LM Surgical Mask Level 3, LM0787: 96 out of 96 passed from 3 |

| | | | | |
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| | article. The particles that passed through the test article are enumerated by a laser particle counter. | particle filtration efficiency of the test article. | | nonconsecutive lots at an average of 99.09%<br><br>LM Surgical Mask Level 2, LM0786: 96 out of 96 passed from 3 nonconsecutive lots at an average of 98.42% |
| Bacterial Filtration Efficiency<br>ASTM F2101 | The BFE test is performed by comparing the bacterial control counts upstream to the bacterial counts downstream of the test article. | The BFE test is performed to determine the bacterial filtration efficiency of test articles. | ≥ 98% | LM Surgical Mask Level 3, LM0787: 96 out of 96 passed from 3 nonconsecutive lots at an average of 99.60%<br><br>LM Surgical Mask Level 2, LM0786: 96 out of 96 passed from 3 nonconsecutive lots at an average of 99.59% |
| Differential Pressure (Delta-P)<br><br>MIL-M-36954C | A controlled flow of air is driven through a sample of the test article containing all layers. The pressure before and after the sample is measured; the difference in pressure is divided by the surface (in cm2) of the sample. | The purpose of this test is to ensure the drop in pressure is not too great so the user may breathe through the subject device. | <6.0mm$H_2O/cm^2$ | LM Surgical Mask Level 3, LM0787: 4.80mm$H_2O/cm^2$<br><br>LM Surgical Mask Level 2, LM0786: 5.20mm$H_2O/cm^2$ |
| Flammability class<br>16CFR 1610 | The test articles are exposed to a flame to determine if they ignite and for how long they burn if ignited. | The purpose of this test is to ensure the subject device does not ignite when exposed to flame. | Class 1 | The test was performed in accordance with 16 CFR 1610 STANDARD FOR THE FLAMMABILITY |

| | | | | |
|---|---|---|---|---|
| | | | | OF CLOTHING TEXTILES to evaluate the flammability of the test sample. Class I<br><br>LM Surgical Mask Level 3, LM0787: 96 out of 96 passed from 3 nonconsecutive lots at Class 1<br><br>LM Surgical Mask Level 2, LM0786: 96 out of 96 passed from 3 nonconsecutive lots at Class 1 |

The performance test results for the LM Surgical Masks meets ASTM F2100-11 Level 3 acceptance criteria. The results demonstrating the safety and effectiveness of the LM surgical masks in their intended environment of use were determined in accordance with the FDA 2004 guidance "Surgical Masks – Premarket Notification [510(k)] Submissions", which outlines performance requirements for surgical masks.

**8. Discussion of Clinical Tests Performed:**

The conclusion drawn from the nonclinical tests demonstrates that the proposed device in 510(K) submission, the LM Surgical Masks (K211378) are as safe, as effective, and performs as well as or better than the legally marketed predicate device K153496.