November 18, 2021

Texas MedPlast LLC
℅ Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K213406
Trade/Device Name: Savvy Mask - Level 3 Surgical Face Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: October 18, 2021
Received: October 19, 2021

Dear Prithul Bom:

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,

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)*
K213406

Device Name
Savvy Mask - Level 3 Surgical Mask

Indications for Use *(Describe)*
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 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.

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

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*"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."*

# K213406 510(k) SUMMARY

This summary of 510(k) is submitted in accordance with the requirements of 21 CFR §807.92:

## I. SUBMITTER

Texas MedPlast LLC
6630 Roxburgh Drive #171
Houston, TX 77041 USA
Tel: +1.832.288.2106
Fax: N/A

Contact Person: Diego Olmos
Date Prepared: September 15, 2021

## II. DEVICE

| | |
|---|---|
| Name of Device: | Savvy Mask – Level 3 Surgical Mask |
| Classification Name: | Surgical Apparel |
| Regulation: | 21 CFR §878.4040 |
| Regulatory Class: | Class II |
| Product Classification Code: | FXX |

## III. PREDICATE DEVICE

| | |
|---|---|
| Predicate Manufacturer: | DemeTECH Corporation |
| Predicate Trade Name: | DemeMASK Surgical Mask |
| Predicate 510(k): | K201479 |

No reference devices were used in this submission.

## IV. DEVICE DESCRIPTION

The Savvy Surgical Face Mask is a disposable, single-use surgical mask. The surgical face masks are non-sterile, 3 layers, flat-pleated style. The outer and inner layers of the face masks consist of a thermal bonded bi-component - polyethylene/polyester nonwoven fabric. The middle layer consists of a melt blown polypropylene filter material. Each mask contains head ties, ear loops or ear bands to secure the mask to the user's face and mouth, as well as a fully enclosed, soft, bendable nosepiece to fit over the nose. This device is not made from natural rubber latex.

## V. INDICATIONS FOR USE

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 provided non-sterile.

## VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVCE

The following characteristics were compared between the subject device and the predicate device in Table 1 below.

### Table 1 – Comparison of Technological Characteristics

| Feature | Subject Device | Predicate Device (K201479) | Result |
|---|---|---|---|
| **Indications for Use** | 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 provided non-sterile. | 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 provided non-sterile. | Same |
| **Materials** | | | |
| Inner Facing Layer | Polyethylene/Polyester Nonwoven | Spun-bond polypropylene | Similar (see conclusion) |
| Middle Layer | Melt blown polypropylene | Melt blown polypropylene | Same |
| Outer Facing Layer | Polyethylene/Polyester Nonwoven | Spun-bond polypropylene | Similar (see conclusion) |
| Nose piece | Galvanized wire coated with polyethylene | Galvanized wire coated with polyethylene | Same |
| Ear loop | Spandex and Nylon – Not made from natural rubber latex | Spandex/nylon | Same |
| Head ties- Tie On | Polyethylene/Polyester nonwoven | N/A | Predicate offers only ear loops |
| Ear Band | Polyethylene/Polyester Nonwoven | N/A | Predicate offers only ear loop |
| **Mask Style** | Flat Pleated | Flat Pleated | Same |
| **Color** | White | White | Same |
| **Dimension (Width), Adult** | 9.5 cm ± 1.0 cm | 9.5 cm ± 1.0 cm | Same |
| **Dimension (Length), Adult** | 17.5 cm ± 1.0 cm | 17.5 cm ± 1.0 cm | Same |

| | | | |
|---|---|---|---|
| **OTC Use** | Yes | Yes | Same |
| **Sterility** | Non-Sterile | Non-Sterile | Same |
| **Use** | Single Use | Single Use | Same |
| **ASTM F2100 Level** | Level 3 | Level 3 | Same |

## VII. PERFORMANCE DATA

The subject device was tested and conformed to the following standards and the requirements stated in the Guidance for Industry and FDA Staff: Surgical Masks – Premarket Notification [510(k)] Submission issued on March 5, 2004. A summary of the benchtop performance testing results is provided below in Table 2.

**Table 2 – Benchtop Performance Testing**

| Item | Proposed Device - Savvy Mask | Acceptance Criteria | Predicate Device DemeMASK (K201479) | Result |
|---|---|---|---|---|
| **Level 3 Fluid Resistance Performance ASTM F1862** | Three non-sequential lots of 32 (total of 96, AQL 4.0) passed at 160mmHg<br>**Lot 1:** 31/32 pass<br>**Lot 2:** 30/32 pass<br>**Lot 3:** 31/32 pass | AQL 4%, single sampling plan, 29 out of 32 Pass at 160mmHg | Pass at 160 mmHg (Level 3 Fluid Resistance) | Pass |
| **Particulate Filtration Efficiency ASTM F2299** | Three non-sequential lots of 32 (total of 96, AQL 4.0) passed at ≥98%<br>**Lot 1:**<br>32/32 pass<br>**Lot 2:**<br>32/32 pass<br>**Lot 3:**<br>32/32 pass | ≥ 98% | Pass at ≥99% | Pass |
| **Bacterial Filtration Efficiency ASTM F2101** | Three non-sequential lots of 32 (total of 96, AQL 4.0) passed at ≥98% -<br>**Lot 1:**<br>32/32 pass<br>**Lot 2:**<br>32/32 pass<br>**Lot 3:**<br>32/32 pass | ≥ 98% | Pass at ≥99% | Pass |
| **Differential Pressure ASTM F2100/EN 14683:2019** | Three non-sequential lots of 32 (total of 96, AQL 4.0) passed at <6.0 H2O/cm2<br>**Lot 1:**<br>32/32 pass<br>**Lot 2:** | AQL 4%, single sampling plan, 29/32 pass<br>< 5.0 $mmH_20/cm^2$ | MIL-M-36954C<br>Average 3.6 mmH2O/cm2 | Pass |

| | | | | |
|---|---|---|---|---|
| | 30/32 pass<br>**Lot 3:**<br>31/32 pass | | | |
| **Class 1 Flammability 16 CFR 1610** | Three non-sequential lots of 32 (total of 96, AQL 4.0) passed Class 1 16 CFR 1610<br>**Lot 1**: Class 1, IBE<br>**Lot 2**: Class 1, IBE<br>**Lot 3**: Class 1, IBE | Class 1<br>< 3.5 second burn time | Class 1 | Pass |

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**Sterilization & Shelf-life Testing**

Not Applicable (This is a non-sterile device and shelf-life is not applicable to this device because of low likelihood of time-dependent product degradation.)

**Biocompatibility Testing**

Biocompatibility testing was performed in accordance with ISO 10993-1:2018. Specifically, the following testing endpoints were evaluated.

**Table 3 - Biocompatibility Testing**

| Biocompatibility Testing Endpoints | Acceptance Criteria | Result |
|---|---|---|
| Cytotoxicity – ISO 10993-5 | Non-Cytotoxic | Pass |
| Skin Sensitization – ISO 10993-10 | Non- Sensitizing | Pass |
| Skin Irritation – ISO 10993-10 | Non-Irritating | Pass |

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**Table 4 – Summary of Non-Clinical Performance Testing**

The following standards have been used to evaluate the Savvy Mask Surgical Mask**:**

| | |
|---|---|
| ASTM F2100 | Standard Specification for Performance of Materials Used in Medical Face Masks |
| ASTM F1862 | Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity) |
| ASTM F2299 | Standard Test Method for Determining the Initial Efficiency of Materials Used in Medical Face Masks to Penetration by Particulates Using Latex Spheres |
| ASTM F2101 | Standard Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus |
| EN 14683:2019 | Standard Test Method for Differential Pressure |
| 16 CFR Part 1610 | Standard for Flammability |
| ISO 10993-1 | Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process |
| ISO 10993-5 | Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity of medical devices |
| ISO 10993-10 | Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization |

**Software Verification and Validation Testing**

Not Applicable (Passive Device)

**Electrical safety and electromagnetic compatibility (EMC)**

Not Applicable (Passive Device)

**Animal Study**

Animal performance testing was not required to demonstrate safety and effectiveness of the device.

**Human Clinical Performance Testing**

Clinical testing was not required to demonstrate the safety and effectiveness of the device.

## VIII. CONCLUSIONS

The conclusions drawn from the performance data demonstrate that the subject device is as safe, as effective, and performs as well as or better than the legally marketed device K201479, DemeMASK Surgical Face Mask manufactured by DemeTECH Corporation.