July 28,2021

Taiji Medical Supplies, Inc.
% Abdel Halim
President, Global and Regulatory Affairs
Global Quality and Regulatory Services
10 Scenic Way
Monroe, New Jersey 08831

Re: K211861
Trade/Device Name: TAIJI Professional Series Level 3 Surgical Face Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical apparel
Regulatory Class: Class II
Product Code: FXX
Dated: July 21, 2021
Received: July 23, 2021

Dear Abdel Halim:

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, 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

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)*
K211861

Device Name
TAIJI Professional Series Level 3 Surgical Face Mask

Indications for Use *(Describe)*
The TAIJI Professional Series Level 3 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 fluid. 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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# 510(k) Summary

This 510(k) Summary is being submitted in accordance with the requirements of *Guidance for Industry and FDA Staff: Surgical Masks – Premarket Notification [510(k)] Submissions*, Issued March 5, 2004 (corrected July 14, 2004).

**1. Device and Company Details:**

510(k) Number: K211861


Submitter / Owner
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| | |
|---|---|
| Date of Preparation of this Summary: | June 10, 2021 |
| Device Trade or Proprietary Name: | TAIJI Professional Series Level 3 Surgical Face Mask |
| Device Common/Usual Name: | Surgical Mask |
| Regulation Name/Device Class/ Product Code: | Surgical Apparel/Class II/FXX |
| Predicate Device Name/K Number: | Premier Guard USA 3 Layer Ear Loop ASTM Level 3 Surgical Face Mask/K202595 |

**2. Device Description:** The TAIJI Professional Series Level 3 Surgical Face Mask is in accordance with the FDA Guidance Document, Surgical Masks – Premarket Notification [510K)] Submissions issued on March 5, 2004. TAIJI Professional Series Level 3 Surgical Face mask is a flat-pleated style mask with elastic ear loops to secure it over the users' mouth and face. The mask consists of three-layers. The inner facing layer is white and is manufactured from spunbond polypropylene (three layers of nonwoven polypropylene). The inner filter material is made of meltblown fiber. The outer facing layer is blue and is manufactured from spunbond polypropylene (three layers of nonwoven polypropylene).

The mask is a single use, disposable device, provided nonsterile.

Intended Use: The TAIJI Professional Series Level 3 Surgical Face Mask is a non- sterile, single-use, disposable mask, intended to be worn in healthcare and surgical procedures.

**3. Technological Characteristics Comparison:**

The following is a summary of the technological characteristics of the TAIJI Professional Series Level 3 Surgical Face Mask as compared to the predicate device.

| Items | Subject Device TAIJI Professional Series Level 3 Surgical Face Mask | Predicate Device K202595 | Comparison |
|---|---|---|---|
| Manufacturer | TAIJI Medical Supplies, Inc. | Premier Guard USA, LLC | N/A |
| 510(k) Number | K211861 | K202595 | N/A |
| FDA Product Code | FXX | FXX | Same |
| Indications for Use | The TAIJI Professional Series Level 3 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 fluid. This is a single use, disposable device, provided non-sterile | The Premier Guard USA 3 Layer Ear Loop ASTM Level 3 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 fluid. This is a single use, disposable device, provided non-sterile | Same |

| | | | | |
|---|---|---|---|---|
| Materials | Inner and Outer Layers | Spun-bond polypropylene | Spun-bond polypropylene | Same |
| | Middle Layer | Melt blown polypropylene filter | Melt blown polypropylene filter | Same |
| | Ear Loops | Polyester with Spandex inner-core | Nylon and Spandex | Similar |
| | Nose Piece | Malleable polyethylene with aluminum wire | Polyethylene laminated soft annealed carbon steel wire | Similar |
| Dimensions | | 17.5cm length x 9.5cm height | 17.5cm length x 9.5cm height | Same |
| Mask Style | | Flat Pleated | Flat Pleated | Same |
| Design Features | | Malleable nosepiece, flat-pleated elastic ear loops | Malleable nosepiece, flat-pleated elastic ear loops | Same |
| Sterility | | Non-sterile | Non-sterile | Same |
| Use | | Single Use, Disposable | Single Use, Disposable | Same |
| Color | | Blue and White | Blue and White | Same |
| ASTM F2100 Level | | Level 3 | Level 3 | Same |
| Biocompatibility | | | | |
| Cytotoxicity<br><br>Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity | | Under conditions of the study, the device considered is cytotoxic (neat and 1:2 extracts were scored 3) | Under conditions of the study, the device is Non-cytotoxic | Fail - Acute Systemic Study was recommended by 3PR and agreed upon by FDA |
| Systemic Study / Systemic Injection Test / ISO GLP ISO 10993-11: Biological evaluation of medical devices – Part 11: Tests for systemic toxicity | | Under conditions of the study, the device is non-cytotoxic | N/A | Pass<br><br>No systemic toxicity: device is not toxic |
| Irritation | | Under conditions of the study, the device is Non-irritating | Under conditions of the study, the device is Non-irritating | Same |

| | | | |
|---|---|---|---|
| Sensitization | Under conditions of the study, the device is Non-sensitizing | Under conditions of the study, the device is Non-sensitizing | Same |
| Fluid Resistance Performance (mmHg) | Pass at 160 mmHg | Pass at 160 mmHg | Same |
| Particulate Filtration Efficiency Performance (%) | Pass at ≥98% | Pass at ≥98% | Same |
| Bacterial Filtration Efficiency Performance (%) | Pass at ≥98% | Pass at ≥98% | Same |
| Differential Pressure (Delta-P) (mm H O/cm ) | Pass at ≤6.0 | Pass at <6.0 | Same |
| Flammability class Class 1 | Pass Class 1 | Pass Class 1 | Same |

## 4. Summary of Non-Clinical Testing

Per FDA document Guidance for Industry and FDA Staff: Surgical Masks – Premarket Notification [510(k)] Submissions, the below testing has been completed on the subject device:

| Standard/Test Methodology | Purpose | Acceptance Criteria | Results |
|---|---|---|---|
| ASTM F1862: Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood | Barrier Testing | At least 29 out of 32 specimens show passing results at 160 mmHg | Samples met the predetermined acceptance criteria |
| ASTM F2101-19: Standard Specification for Performance of Materials Used in Medical Face Masks | Barrier Testing | ≥98% | Samples met the predetermined acceptance criteria 96 Samples, 3 non-consecutive lots of 32 each |
| EN 14683:2019 Annex C and ASTM F2100-19: Standard Specification for Performance of Materials Used in Medical Face Masks | Physical Testing | <6.0 mm $H_2O/cm^2$ | Samples met the predetermined acceptance criteria 96 Samples, 3 non-consecutive lots of 32 each |
| ASTM F2100-19: Standard Specification for Performance of Materials Used in Medical Face Masks | Barrier Testing | ≥98% | Samples met the predetermined acceptance criteria 96 Samples, 3 non-consecutive |

| | | | |
|---|---|---|---|
| | | | lots of 32 each |
| 21 CFR 1610 | Safety Testing | Class 1, Does not ignite | Samples met the predetermined acceptance criteria 96 Samples, 3 non-consecutive lots of 32 each |
| ISO 10993-5: Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity | Safety Testing | Non-cytotoxic | Fail |
| ISO 10993-11: Biological evaluation of medical devices – Part 11: Tests for systemic toxicity | Safety Testing | Under conditions of the study, the device is non- cytotoxic | Pass No systemic toxicity: device is not toxic |
| ISO 10993-10: Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization | Safety Testing | Non-irritating | Pass |
| ISO 10993-10: Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization | Safety Testing | Non- sensitizing | Pass |

## 5. Conclusion:

The conclusions drawn from the nonclinical tests demonstrate that the subject device K211861 TAIJI Medical Professional Series Level 3 Surgical Face Mask is as safe, as effective and performs as well or better than the legally marketed predicate device, K202595 Premier Guard USA 3 Layer Ear Loop ASTM Level 3 Surgical Face Mask.