April 23, 2020

Mexpo International Inc.
Tim Thai
President
2828 Faber Street
Union City, California 94587

Re: K200847
Trade/Device Name: Avianz® Surgical Face Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: April 2, 2020
Received: April 6, 2020

Dear Mr. Thai:

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,

CAPT Elizabeth Claverie, MS
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K200847

Device Name

Avianz® Surgical Face Mask

Indications for Use *(Describe)*

When properly worn, the surgical face masks are intended to protect both patient and healthcare workers from transfer of microorganisms, body fluids and airborne particles. This device is non sterile and for single use only.

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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510K SUMMARY

Date of Summary Prepared: April 20, 2020

510K Number: K200847

1. Applicant : MEXPO INTERNATIONAL INC.
   Address : 2828 Faber Street, Union City, CA 94587, U.S.A.
   Tel : 510 – 489 6800
   Fax : 510 – 489 3111
   E-mail : mexpoglove@aol.com

   Official Correspondence: Tim Thai (President)

2. **Device Name: Avianz®** Surgical Face Mask

3. **Regulatory Information**
   Classification Name : Surgical Face Mask, Apparel
   Classification : Class II
   Product Code : FXX
   Regulation Number : 21 CFR 878.4040

4. **Predicate Device**
   510K Number : K911334 - Thai Hospital Products Co. Ltd.
   Device Name : Mask, Surgical Apparel

5. **Intended Use**
   When properly worn, the surgical face masks are intended to protect both patient and healthcare workers from transfer of microorganisms, body fluids and airborne particles. This device is non-sterile and for single use only.

6. **Device Description**
   The surgical face masks are non-sterile, single use, 3 layers, flat-pleated style with ear loops and nose piece. The outer layer and inner facing layer of face mask consist of Spunbond Polypropylene, and the middle layer consists of Melt Blown Polypropylene Filter. Each mask contains ear loops to secure the mask over the user's face and mouth with nose piece to firmly fit over the nose. This device is not made from any natural rubber latex.

7. Summary of Comparison and Technological Characteristics

Table 1 - General Comparison

Device	Proposed Device	Predicate Device	Result
Manufacturer	MEXPO INTERNATIONAL INC.	Thai Hospital Products Co. Ltd.	-
510K Number	K200847	K911334	-
Product Common Name	SURGICAL FACE MASK	SURGICAL FACE MASK	Same
Product Code	FXX	FXX	Same
Classification	Class II (21 CFR 878.4040)	Class II (21 CFR 878.4040)	Same
Intended Use	When properly worn, the surgical face masks are intended to protect both patient and healthcare workers from transfer of microorganisms, body fluids and airborne particles. This device is non-sterile and for single use only.	When properly worn, the surgical face masks are intended to protect both patient and healthcare workers from transfer of microorganisms, body fluids and airborne particles. This device is non-sterile and for single use only.	Same
Model	3 Ply, Ear Loops, Flat-Pleated Style	3 Ply, Ear Loops or Tie-On	Similar

Materials			
Outer Facing Layer	Spunbond Polypropylene	Spunbond Polypropylene	Same
Middle Layer	Melt Blown Polypropylene Filter	Melt Blown Polypropylene Filter	Same
Inner Facing Layer	Spunbond Polypropylene	Spunbond Polypropylene	Same
Nose Piece	Single Galvanize Wire, Coated By PE	Single Galvanize Wire, Coated By PE	Same
Ear Loops	not made with natural rubber latex	not made with natural rubber latex	Same
Color	White	Blue, Pink, Yellow, Green, Orange, Purple, White & Multi Color	Similar
Dimension (Width)	9.0cm ± 0.5cm	9.0cm ± 0.5cm	Same
Dimension (Length)	17.5cm ± 0.5cm	17.5cm ± 0.5cm	Same
OTC Use	Yes	Yes	Same
Sterility	Non-Sterile	Non-Sterile	Same
Use	Single Use	Single Use	Same
ASTM F2100 Level	Level 2	Level 2	Same

8. Non-clinical Tests Performed on the Proposed Device

The proposed 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.

Table 2 - Performance Testing

Item	Proposed Device	Acceptance Criteria	Result
Fluid Resistance Performance ASTM F1862	30 Out of 32 pass at 120 mmHg	29 Out of 32 pass at 120 mmHg	Pass
Particulate Filtration Efficiency ASTM F2299	99.9%	≥ 98%	Pass
Bacterial Filtration Efficiency ASTM F2101	> 99.9%	≥ 98%	Pass
Differential Pressure (Delta P) MIL-M-36954C	3.0 mmH_20/cm^2	< 5.0 mmH_20/cm^2	Pass
Flammability 16 CFR 1610	Class 1	Class 1	Pass

Table 3 - Biocompatibility Testing

Item	Proposed Device	Acceptance Criteria	Result
Results	Non-Cytotoxic, Non-Sensitizing, Non-Irritating	Non-Cytotoxic, Non-Sensitizing, Non-Irritating	Pass

9. Conclusion

There is no clinical study included in this submission. The conclusion drawn from the non-clinical tests demonstrates that the subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate device.