January 13, 2023

JSN Holdings, LLC
% John F. Gillespy, MBA
President
FDA 510K Consultants, LLC
1100 Del Lago Circle #104
Palm Beach Gardens, Florida 33410

Re: K221682
Trade/Device Name: Ideal Med Pro 3-Ply Disposable Face Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: November 28, 2022
Received: December 5, 2022

Dear Mr. Gillespy:

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,

Brent Showalter -S

Brent Showalter, Ph.D.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K221682

Device Name
IDEAL MED PRO 3-PLY DISPOSABLE FACE MASK

Indications for Use *(Describe)*

When properly worn, the surgical face mask is 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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"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."

510(k) Summary

Prepared in accordance with the requirements of 21 CFR Part 807.92.

1. 510(k) Submitter:

JSN Holdings, LLC
1735 Dilworth Road East, Matthews, NC 28203
Phone: 201-247-5838
Email: brian@bpamericas.com

2. Company Contact: Brian Tedesco, President

3. Date of Submission: September 10, 2022

4. 510(k) Preparer:

John F. Gillespy, MBA
FDA 510k Consulting, LLC
Palm Beach Gardens, FL 33410
Phone: 386-243-4332
Email: john@fda510kconsultants.com

5. Device Classification:

Trade name:	Ideal Med Pro 3-Ply Disposable Face Mask
Common name:	Surgical Face Mask
Device:	Surgical Mask
Class:	II
Regulation #:	878.4040
Product Code:	FXX

6. Predicate:

Applicant:	Mexpo International, Inc.
Device:	Avianz Surgical Face Mask
510(k) Number:	K200847

7. <u>Device Description</u>

Ideal Med Pro 3-Ply Disposable Face Mask is a 3-ply, flat-pleated style surgical mask. The device is manufactured with three layers. The inner and outer layers are made of spunbond polypropylene, and the middle layer is made of melt blown polypropylene filter. Each mask contains elastic ear loops to secure the mask over the user's face and mouth with nose piece to fit firmly over the nose.

This device is not made from any natural rubber latex.

The product is sold non-sterile and intended to be disposable for single-use.

8. Indications For Use

When properly worn, the surgical face mask is 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.

The device is intended for OTC use.

9. Comparison To Predicate Device

Ideal Med Pro 3-Ply Surgical Face Mask is compared to a predicate device, Avianz Surgical Face Mask (K200847). The predicate selection conforms to FDA's guidance document, "Evaluating Substantial Equivalence in Premarket Notifications [510(k)]" (July 2014).

Comparison Table

Device	Proposed Device	Predicate Device	Comparison
Manufacturer	JSN Holdings, LLC	Mexpo International, Inc.	-
510K Number	K221682	K200847	-
Product 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 mask is 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, Flat-Pleated Style	Same
Materials, Dimensions, & Other Features			
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	Blue (inner facing) & white	White	Similar
Dimension (Width)	9.5cm ± 0.5cm	9.0cm ± 0.5cm	Similar
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, Disposable	Single Use, Disposable	Same
Testing			
Performance Level:			
ASTM F2100:2019	Level 2	Level 2	Same
Bacterial Filtration	99.9%	98%	Both Pass
Particle Filtration	99.9%	98%	Both Pass
Fluid Resistance	93 of 96 pass @ 120 mmHg	29 of 32 pass @ 120 mmHg	Both Pass
Differential Pressure	< 5.0 mmH_2O/cm^2	< 5.0 mmH_2O/cm^2	Both Pass
Flammability	Class 1	Class 1	Same
Biocompatibility:			
Cytotoxicity	Not Cytotoxic	Not Cytotoxic	Same
Sensitization	Not Skin Sensitive	Not Skin Sensitive	Same
Irritation	Not Skin Irritating	Not Skin Irritating	Same

Ideal Med Pro 3-Ply Surgical Face Mask is comparable to the predicate device (K200847) in terms of materials and performance, except that the subject meets Level 1 performance rating while the predicate performs to Level 2 specifications.

The reference device (K060776) is introduced to demonstrate substantial equivalence for this performance difference. The reference could in fact have served as a predicate except for the lack of detailed specifications included in its 510k Summary and the absence of such information available to the public. Both the subject and reference devices are face masks with comparable construction and materials, and both meet Level 1 testing performance to the same FDA-recognized standard, ASTM F2100.

In summary, none of the differences noted in the Comparison Table raise new issues of safety or effectiveness.

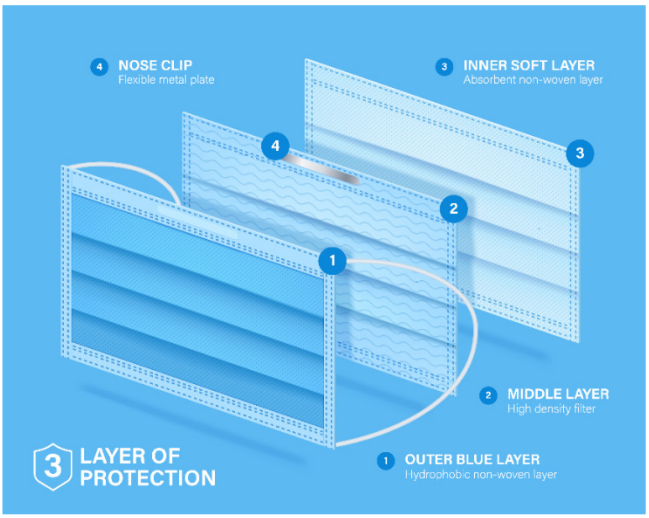
10. Summary Of Non-Clinical Testing

The following performance data has been provided to demonstrate that the subject device meets the acceptance criteria in the standard.

Non-Clinical Testing Table

Test Standard	Purpose	Acceptance Criteria	Results
ASTM F2101	Bacterial Filtration Efficiency (BFE)	98%	99.9%
ASTM F2299	Particulate Filtration Efficiency (PFE)	98%	99.9%
ASTM F1862	Synthetic Blood Fluid Resistance	29 out of 32 pass at 120 mmHg	30, 31, and 32 pass at 120 mmHg, out of 32 test articles in each of three lots (96 total test articles)
MIL-M-36954C	Differential Pressure (Delta P)	< 5.0 mmH_20/cm^2	4.2 - 4.9 mmH_20/cm^2 in 8 test articles in each of three lots (24 total test articles)
16 CFR 1610	Flammability	IBE = Test article ignited but exting-uished, burn time > 3.5 sec (Class 1)	IBE for all 8 test articles in each of 3 lots (24 total test articles)

11. Patient-Contacting Materials



Materials composition follows:

- Outer facing layer – spunbond polypropylene (blue)
- Middle layer – melt blown polypropylene filter (white)
- Inner facing layer – spunbond polypropylene (white)
- Nose piece – white aluminum strip with polypropylene covering
- Ear loops – spandex and nylon, not made from natural rubber latex (white)

The outer & inner layers and ear loops touch the patient's face and hands. Type and duration of contact with patient follows:

- Surface contact – intact skin
- Limited duration – less than 24 hours

12. Software Verification and Validation… The mask contains no software or firmware.

13. Substantial Equivalence

Many of the subject device's features and technical characteristics are identical to those of the predicate device, and where there are differences, such differences do not have an impact on the safety or effectiveness of the subject device.

The subject device successfully followed the pathway to Substantial Equivalence in the FDA guidance document, "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications" (2014). The steps are summarized below:

- The predicate device is legally marketed and was found substantially equivalent through 510(k) premarket submission.
- The subject and predicate devices have the same intended use (and indications for use).
- Technological differences between the subject and predicate were evaluated; none of the differences raised different issues of safety and effectiveness.
- The following methods for evaluation of the effects of different characteristics on safety and effectiveness were deemed acceptable—testing for performance characteristics and biocompatibility. All evaluation methods were conducted to FDA-recognized standards.
- Data from these tests demonstrated equivalence and support the indications for use.

In summary, all necessary testing has been performed and the results support the conclusion that Ideal Med Pro 3-Ply Surgical Face Mask is substantially equivalent to the legally marketed predicate based on both (a) comparison of intended use, materials, technology, and design and (b) testing to FDA-recognized standards, and the device thus does not raise any concerns of safety or effectiveness.

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(k) submission K202516, Ideal Med Pro 3-Ply Disposable Face Mask, is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K200847.