March 14, 2022

DWFritz Automation, Inc.
% John Gillespy
President
FDA 510k Consultants, LLC
1100 Del Lago Circle
Palm Beach Gardens, Florida 33410

Re: K213894
Trade/Device Name: DWFritz ASM2000
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical apparel
Regulatory Class: Class II
Product Code: FXX
Dated: December 10, 2021
Received: December 14, 2021

Dear John 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,

Bifeng Qian
Acting 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)*
K213894

Device Name
DWFritz ASM2000

Indications for Use *(Describe)*
When properly worn, DWFritz ASM2000 surgical face mask is intended to protect both the patient and healthcare worker from transfer of microorganisms, body fluids and particulate matter. The 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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510(k) Summary_K213894

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

1. 510(k) Submitter:

DWFritz Automation, Inc.
9600 SW Boeckman Rd., Wilsonville OR 97070
Phone: 503-885-7030
Email: cpsmith@dwfritz.com

2. Company Contact: Curtis Smith, Senior Quality Manager

3. Date of Submission: December 10, 2021

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:	DWFritz ASM2000
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. Device Description

DWFritz ASM2000 is a 3-ply, flat-pleated style surgical face 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 ear loops made of polyester filament and spandex fiber to secure the mask over the user's face and mouth with galvanized wire nose bridge 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, **DWFritz ASM2000** surgical face mask is intended to protect both the patient and healthcare worker from transfer of microorganisms, body fluids and particulate matter. This device is non-sterile and for single use only.

The device is intended for OTC use.

9. Comparison To Predicate Device

DWFritz ASM2000 is compared to a predicate device, Avianz Surgical Face Mask (K200847).

Comparison Table

Device	Proposed Device	Predicate Device	Comparison
Manufacturer	DWFritz Automation, Inc.	Mexpo International, Inc.	-
510K Number	K213894	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, **DWFritz ASM2000** surgical face mask is intended to protect both the patient and healthcare worker from transfer of micro-organisms, body fluids and particulate matter. 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, flat-pleated style with ear loops and nose bridge	3-Ply, Flat-Pleated Style with ear loops and nose bridge	Same
Materials, Dimensions, & Other Features			
Outer Facing Layer	Spunbond Polypropylene	Spunbond Polypropylene	Same
Middle Layer	Meltblown Polypropylene	Meltblown Polypropylene	Same
Inner Facing Layer	Spunbond Polypropylene	Spunbond Polypropylene	Same
Nose Bridge	Galvanized wire with polyester coating	Galvanized wire with polyester coating	Same

Ear Loops	Not made with natural rubber latex	Not made with natural rubber latex	Same
Color	Blue (inner facing) & white	White	Similar
Dimension (W X L)	9.8 X 17.2 ± 0.5cm	9.5 X 17.5 ± 0.5cm	Similar
Use	OTC, single use, disposable	OTC, single use, disposable	Same
Sterility	Non-Sterile	Non-Sterile	Same
Testing			
Performance Level:			
ASTM F2100:2019	Level 2	Level 2	Same
Bacterial Filtration	99.9%	98%	Both Pass
Particle Filtration	98.4%	98%	Both Pass
Fluid Resistance	94 of 96 pass @ 120 mmHg	29 of 32 pass @ 120 mmHg	Both Pass
Differential Pressure	< 4.7 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

DWFritz ASM2000 is comparable to the predicate device (K200847) in terms of materials, performance, and biocompatibility.

10. Summary Of Non-Clinical Testing

The following performance data has been provided to demonstrate that **DWFritz ASM2000** meets the acceptance criteria in the standard.

Non-Clinical Testing Table

Test Standard	Purpose	Acceptance Criteria	Results
ISO 10993-05	Cytotoxicity	< Grade 2 cytotoxic effect	Grade 1 (slight reactivity)
ISO 10993-10	Skin Sensitization	No sensitization reaction	No sensitization reaction
ISO 10993-10	Skin Irritation	No irritation reaction	No irritation reaction
ASTM F2101	Bacterial Filtration Efficiency (BFE)	98%	99.9%
ASTM F2299	Particulate Filtration Efficiency (PFE)	98%	98.8-99.7% in 32 test articles in each of three lots (96 total test articles)

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	2.9 - 4.7 mmH_20/cm^2 in 32 test articles in each of three lots (96 total test articles)
16 CFR 1610	Flammability	IBE = Test article ignited but exting-uished, burn time > 3.5 sec (Class 1)	IBE for all 14 test articles in each of 3 lots (42 total test articles)

11. Patient-Contacting Materials

    Materials composition follows:

    - Outer facing layer – spunbond polypropylene (blue)
    - Middle layer – meltblown polypropylene filter (white)
    - Inner facing layer – spunbond polypropylene (white)
    - Nose bridge – Galvanized wire with polyester coating
    - Ear loops – polyester filament & spandex fiber, 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.

The conclusion drawn from the nonclinical tests demonstrates that the subject device, **DWFritz ASM2000**, is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K200847.