March 27, 2023

Efofex, Inc.
% Timothy Kania
Official Correspondent
mdi Consultants, Inc.
55 Northern Blvd, Suite 200
Great Neck, New York 11021

Re: K223823
Trade/Device Name: Disposable Surgical Face Mask
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: December 20, 2022
Received: December 21, 2022

Dear Timothy Kania:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K223823

Device Name
Disposable Surgical Mask

Indications for Use *(Describe)*

This single-use surgical mask EFXPLY3SMSK is intended to be worn to protect both the patient and health care 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 of blood and body fluids. This is a single use, disposable device, 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.

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510(K) Summary

Contact Details K223823

A. Applicant Details

Applicants Name	Efofex, Inc.
Applicants Address	1300 N Dixieland Road, Rogers, AR 72758
Contact Person	Siddhant Doshi
Phone Number	917-213-2740
E-mail	sid@efofexinc.com
Date Prepared	12/14/22

Official Correspondent

Contact Person	Tim Kania
Company Name	mdi Consultants, Inc.
Address	55 Northern Blvd. Suite 200 Great Neck, NY 11021
Phone	516-482-9001
Email	Tim@mdiconsultants.com

B. Device Information

Trade Name	Disposable Surgical Mask
Common Name	Disposable Surgical Mask
Model	EFX3PLYSMSK
Classification	II
Classification Name	Mask, Surgical
Product Code	FXX
Regulation No.	21 CFR 878.4040

C. Legally Marketed Primary Predicate Device

Trade Name	Surgical Face Mask, Model GFYY95
510 (K)	K202761
Product Code	FXX
Manufacturer	Guangdong Good Feeling Hygiene Material Tec Co., LTD.

D. Indications for use of the device

This single-use surgical mask EFXPL Y3SMSK is intended to be worn to protect both the patient and health care 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 of blood and body fluids. This is a single use, disposable device, non-sterile.

E. Device description

The device is a flat pleated type mask the outer layer being blue and the inner layer being white, utilizing ear loops to secure the mask in place, and a nose bridge is also incorporated for a proper fit around the nose. The device number is EFX3PLYSMSK.

The device is manufactured with three layers, the inner and outer layers are made of spun bond polypropylene, and the middle layer is made of melt-blown polypropylene filter material. The model EFX3PLYSMSK device is held in place over the user's mouth and nose by two elastic ear loops welded to the face mask. The elastic ear loops are made of polypropylene and spandex. The nose bridge contained within the device is placed between the layers of the surgical mask to allow the user to fit the surgical mask properly around their nose. The nose bridge is made up of galvanized wire coated with polyethylene.

F. Technological Characteristics Comparison with primary predicate device

DEVICE	PROPOSED DEVICE	PRIMARY PREDICATE DEVICE	COMPARISON
Manufacturer	Efofex, Inc 1300 N Dixieland Road Rogers AR 72758	Guangdong Good Feeling Hygiene Material Tec Co. LTD. 10 Phoenix Av. Eco-Industrial Pk. Guangdong Province, China	NA
510K	K223823	K202761	NA
Classification	Class II Device, FXX (21CFR878.4040)	Class II Device, FXX (21CFR878.4040)	Similar
Indications for use	This single use surgical mask EFX3PLY3SMSK is intended to be worn to protect both the patient and health care 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, disposal device, provided non-sterile.	This single use surgical mask GFYY95 is intended to be worn to protect both the patient and health care 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, disposal device, provided non-sterile.	Similar
Description	Ear loops, flat pleated, three layers	Ear loops, flat pleated, three layers	Similar
Outer layer	Spun-bond polypropylene	Spun-bond polypropylene	Similar
Middle layer	Melt-blown polypropylene filter	Melt-blown polypropylene filter	Similar
Inner layer	Spun- bound polypropylene	Spun- bound polypropylene	Similar
Nose bridge	Galvanized wire with polyethylene coating	Galvanized wire with polyethylene coating	Similar
Ear loops	Polypropylene & Spandex	Nylon & Spandex	Different[1]
Color	Blue	Blue	Similar
Length	175 mm	180mm	Different[2]
Width	95 mm	95mm	Similar
OTC use	Yes	Yes	Similar

Sterility	No	No	Similar
Use	Single use, Disposable	Single use, Disposable	Similar
ASTM F2100 level	Level 2 & 3	Level 3	Similar[3]
Biocompatibility	ISO10993	ISO10993	Similar

Discussion of Similarities and Differences

1: Differences in Ear Loop material have no effect on the safety or efficacy of the device. The subject device was tested for Biocompatibility and passed. Please see table 3 below for a summary of the Biocompatibility testing.

2: Differences in Dimensions have no effect on the safety or efficacy of the device. Please see table 2 below for a summary of the performance testing performed on this device.

3: The Level 2 and Level 3 masks are comprised of the same material which has passed performance testing for Level 3 protection. This has no effect on the safety or performance of the device.

G. Nonclinical test conclusion

Non-clinical tests were conducted to verify that the proposed device met all design specifications as was similar to the predicate device. The test results demonstrated that the proposed device meets the acceptance criteria for the following standards and the requirements stated in the guidance for industry and FDA staff; surgical mask-premarket notification (510 K).

ISO 10993-5: 2009 Biological evaluation of medical devices - part 5:
Test for In vitro cytotoxicity

ISO 10993-10: 2010 Biological Evaluation of Medical Devices – part 10:
Test for irritation and skin sensitization

ASTM F2100, Standard Specification for performance of Materials Used in 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);

EN 14683, Medical Face Masks -- Requirements and Test Methods;

ASTM F2101, Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) Of Medical Face Mask Materials Using a Biological Aerosol of Staphylococcus Aureus;

ASTM F2299, Stand test method for determining the initial efficiency of materials used in medical face masks to penetration by particulates using latex spheres;

16 CFR 1610, Standard for the Flammability of clothing textiles;

Table 2 – Performance Testing Level 3			
Test Methodology	**Proposed Device EFX3PLYSMSK**	**Accepted Criteria Level 3**	**Result**
Fluid Resistance Performance ASTM F1862	95 of 96 samples passed	160mm Hg.	Pass
Particulate Filtration Efficiency ASTM F2299	99.79% Filtration average efficiency across 96 samples	≥98%	Pass
Bacterial Filtration Efficiency ASTM F2101-19	99.8% Filtration average efficiency across 96 samples	≥98%	Pass
Differential Pressure (Delta P) AMST F2100-19	3.56 mm H_2O/cm^2 average pressure drop across 96 samples	<6.0mm H_2O /cm^2	Pass
Flammability 16 CFR 1610	96 of 96 samples did not ignite	Class 1	Pass

Table 3 – Performance Testing Level 2			
Test Methodology	**Proposed Device EFX3PLYSMSK**	**Accepted Criteria Level 2**	**Result**
Fluid Resistance Performance ASTM F1862	96 of 96 samples passed	120mm Hg.	Pass
Particulate Filtration Efficiency ASTM F2299	99.79% Filtration average efficiency across 96 samples	≥98%	Pass
Bacterial Filtration Efficiency ASTM F2101-19	99.8% Filtration average efficiency across 96 samples	≥98%	Pass
Differential Pressure (Delta P) AMST F2100-19	3.56 mm H_2O/cm^2 average pressure drop across 96 samples	<6.0mm H_2O /cm^2	Pass
Flammability 16 CFR 1610	96 of 96 samples did not ignite	Class 1	Pass

Table 4 – Biocompatibility Testing			
Item	**Proposed Device**	**Accepted Criteria**	**Result**
Cytotoxicity	Under the conditions of the study, the subject device extract did not show potential toxicity to L 929 cells	No potential cytotoxicity	Pass
Irritation	Under the condition of the study, the device is non-irritating	Non-irritating	Pass
Sensitization	Under the conditions of the study, the device is non sensitizing	Non-sensitizing	Pass

H. Clinical Test Conclusions

No clinical tests is included in this submission

I. Conclusion

Based on the nonclinical tests performed, the subject device is as safe, is effective, and performs as well or better than the legally marketed primary predicate device number K202761, manufactured by Guangdong Good Feeling Hygiene Material Tec Co. LTD, single use surgical mask.