February 19, 2026

Efofex, Inc.
% Vaibhav Rajal
Official Correspondent for Efofex Inc
mdi Consultants Inc
55 Northern Blvd, Suite 200
Great Neck, New York 11021

Re: K253398
Trade/Device Name: Disposable Surgical Mask (Non-Sterile) (EFX3PLBLKMSK300)
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: Class II
Product Code: FXX
Dated: January 22, 2026
Received: January 22, 2026

Dear Vaibhav Rajal:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

ALLAN GUAN -S

For Bifeng Qian, M.D., Ph.D.
Assistant Director
DHT4C: Division of Infection
Control 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K253398

Device Name
Disposable Surgical Mask (Non-Sterile) (EFX3PLBLKMSK300)

Indications for Use *(Describe)*
This single use surgical mask EFX3PLBLKMSK300 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.

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

K253398

Contact Details

1. Applicant Details

Applicants Name	Efofex, Inc.
Applicants Address	1300 N Dixieland Road, Rogers, AR 72758
Contact Person	Siddhant Doshi
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E-mail	sid@efofexinc.com
Date Prepared	February 18, 2026

2. Official Correspondent

Contact Person	Vaibhav Rajal
Company Name	mdi Consultants, Inc.
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Phone	516-482-9001
Email	vaibhav@mdiconsultants.com

3. Alternate Official Correspondent:

Contact Person	Ms. Susan D. Goldstein-Falk
Company Name	mdi Consultants, Inc.
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Phone	516-482-9001
Email	sgoldstein@mdiconsultants.com

4. Device Information

Trade Name	Disposable Surgical Mask (Non-Sterile) (EFX3PLBLKMSK300)
Common Name	Disposable Surgical Mask
Model	EFX3PLBLKMSK300
Classification	II
Classification Name	Mask, Surgical
Product Code	FXX
Regulation No.	21 CFR 878.4040

5. **Legally Marketed Predicate Device**

510(k) Number	K223823
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

6. Indications for use of the device

This single use surgical mask EFX3PLBLKMSK300 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.

7. Device description

Device name: Disposable Surgical Mask Model Number: EFX3PLBLKMSK300

The device is a flat pleated type of mask the outer layer being black and the inner layer being black, 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 EFX3PLBLKMSK300.

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 EFX3PLBLKMSK300 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 form the surgical mask properly around their nose. The nose bridge is made up of galvanized wire coated with polyethylene

8. Technological Characteristics Comparison with predicate device

Parameters	Proposed Subject Device	Proposed Predicate Device	Comparison
510(k) Number	K253398	K223823	
Manufacturer	Efofex	Efofex	Same
Device Name	Disposable Surgical Mask (Non-Sterile) (EFX3PLBLKMSK300)	Disposable Surgical Mask	Similar
FDA Product Code	FXX	FXX	Same
Classification	Class II, 21CFR 878.4040	Class II, 21CFR 878.4040	Same
Model	EFX3PLBLKMSK300	EFX3PLYSMSK	Similar
Indications for Use Statement	This single use surgical mask EFX3PLBLKMSK300 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 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.	Similar
Description	Ear loops, flat pleated, three layers	Ear loops, flat pleated, three layers	Same
Outer Layer	Spun-bond polypropylene	Spun-bond polypropylene	Similar
Middle Layer	Melt-blown polypropylene filter	Melt-blown polypropylene filter	Same
Inner layer	Spun- bound polypropylene	Spun- bound polypropylene	Same
Nose Bridge	Galvanized wire with polyethylene coating	Galvanized wire with polyethylene coating	Same
Ear Loops	Polypropylene & Spandex	Polypropylene & Spandex	Same
Color	Black	Blue	Different
Length	175 mm	175 mm	Same
Width	95 mm	95 mm	Same
Rx or OTC	OTC	OTC	Same
Sterility	No	No	Same
Use	Single Use, Disposable	Single Use, Disposable	Same
ASTM Level	Level 2 & Level 3	Level 2 & Level 3	Same

Biocompatibility	Under the conditions of the testing, not an irritant, not a sensitizer, and non-cytotoxic	Under the conditions of the testing, not an irritant, not a sensitizer, and non-cytotoxic	Same

Discussions of Similarities and Differences

The proposed subject device, **Model EFX3PLBLKMSK300**, is identical to our predicate device, **K223823 (Model EFX3PLYSMSK)**, in all respects **except for the color**. The only difference is that the subject device is **black**, whereas the predicate device is **blue**. Aside from this cosmetic variation, both devices are equivalent in terms of design, materials, intended use, manufacturing process, and performance characteristics.

9. 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 F2100-23, 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 F3502, Standard Specification for Barrier Face Coverings;
- 16 CFR 1610, Standard for the Flammability of clothing textiles, Class 1.

Test Method / Standard	Purpose	Acceptance Criteria	Result
BIOCOMPATIBILITY TESTING			
In Vitro Cytotoxicity ISO 10993-5:2009	Evaluate potential toxic effects on cells	Under the conditions of the study, the test material	Pass

		should not exhibit cytotoxic effects	
Skin Irritation ISO 10993-10:2010	Evaluate potential to cause skin irritation	Under the conditions of the study, the test material should not cause skin irritation	Pass
Skin Sensitization ISO 10993-10:2010	Evaluate potential to cause allergic skin reactions	Under the conditions of the study, the test material should not cause sensitization	Pass
PERFORMANCE TESTING			
Fluid Resistance Performance ASTM F1862	Evaluate protection against blood and body fluid exposure	Masks must resist penetration by synthetic blood at specified pressure levels (120 mmHg for Level 2; 160 mmHg for Level 3)	Pass
Sub-Micron Particulate Filtration Efficiency ASTM F3502	Evaluate filtration efficiency for sub-micron particles at specified face velocity to determine barrier performance level	≥85% sub-micron particulate filtration efficiency	Pass
Bacterial Filtration Efficiency (BFE) ASTM F2101	Evaluate filtration efficiency using biological aerosol of Staphylococcus aureus	≥98% bacterial filtration efficiency	Pass
Differential Pressure (Delta P) ASTM F2100-23 / EN 14683	Evaluate breathability	<6.0 mmH_2O/cm^2	Pass
Flammability 16 CFR 1610	Ensure the mask material meets flammability safety requirements	Class 1 (normal flammability; material should not ignite readily)	Pass
Overall ASTM Performance Level ASTM F2100-23	Verify overall performance requirements for medical face masks	Meet Level 2 and Level 3 performance requirements	Pass

10. Conclusion

The conclusions drawn from the non-clinical tests demonstrate that the subject device, Disposable Surgical Face Mask (Non-Sterile) (EFX3PLBLKMSK300), is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under K223823.