January 21, 2021

Aerobiotix, Inc.
% Rafael Aguila
Responsible Third-Party Official
Accelerated Device Approval Services
6800 S.W. 40th Street, Ste. 403
Ludlum, Florida 33155

Re: K203189
Trade/Device Name: Aerocure-md
Regulation Number: 21 CFR 880.6500
Regulation Name: Medical Ultraviolet Air Purifier
Regulatory Class: Class II
Product Code: FRA
Dated: January 5, 2021
Received: January 6, 2021

Dear Rafael Aguila:

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,

Clarence W. Murray, III, PhD
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K203189

Device Name

AEROCURE-MD Medical Air Purifier

Indications for Use *(Describe)*

The Aerobiotix AEROCURE-MD air purifier is a device intended for medical purposes that is used to destroy bacteria and viruses in the air by exposure to ultraviolet radiation. In addition, the device removes particles from the air via HEPA filtration.

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: K203189

SUBMITTER INFORMATION:

Company Name:	Aerobiotix, Inc. 444 Alexandersville Road Miamisburg, OH 45342 Telephone (888) 978-7087 FAX (937) 388-8145
Official Contact:	David Kirschman, M.D. President
Date Prepared:	January 21st, 2021

DEVICE INFORMATION:

Trade/Proprietary Name:	AEROCURE-MD Medical Air Purifier
Common Name:	Ultraviolet Medical Air Purifier
Device Class:	Class II
Regulation Number:	21 CFR 880.6500
Product Code:	FRA
Classification Name:	Medical Ultraviolet Air Purifier
Category:	General Hospital

PREDICATE DEVICES:

Biological Controls MICROCON 800MUV K972064

INTENDED USE:

The Aerobiotix AEROCURE-MD air purifier is a device intended for medical purposes that is used to destroy bacteria and viruses in the air by exposure to ultraviolet radiation. In addition, the device removes particles from the air via HEPA filtration.

DEVICE DESCRIPTION:

The AEROCURE-MD is a free-standing flow-through air purification device which uses germicidal ultraviolet light with supplemental HEPA filtration to remove airborne contamination. The AEROCURE-MD device has a wheeled metal housing with electrical controls and outer dimensions of 74 x 62 x 178 cm which is placed within a room. The device has a pleated pre-filter, ultraviolet photolytic chamber equipped with germicidal ultraviolet lamps, and a 99.97% HEPA filter. The AEROCURE-MD is for over-the-counter use.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE:

The AEROCURE-MD has the following technical characteristics as the Biological Controls MICROCON MAP-800M (K974682) predicate device:

Element of Comparison	Aerobiotix AEROCURE-MD	Biological Controls MICROCON MAP-800M (K974682)	Comparison
Device Type	Medical UV Air Purifier	Medical UV Air Purifier	Same
Product Code	FRA	FRA	Same
Regulation #	21 CFR 880.6500	21 CFR 880.6500	Same
Indications for use	The AEROCURE-MD air purifier is a device intended for medical purposes that is used to destroy bacteria and viruses in the air by exposure to ultraviolet radiation. In addition, the device removes particles from the air via HEPA filtration.	Used for filtering airborne particles from air for medical purposes.	Similar
First Mechanism of Action	HEPA filtration	HEPA filtration	Same
Second Mechanism of Action	Ultraviolet germicidal lamps	Ultraviolet germicidal lamps	Same
Construction	Wheeled portable enclosure	Wheeled portable enclosure	Same
Voltage	120V/60 Hz	120V/ 60 Hz	Same
Electrical certification	Applicable UL Standards compliant, IEC 60601-1-2	Applicable UL Standards compliant	Similar, the subject device is compatible with IEC 60601-1-2
Clean air outflow	300-450 CFM (“Cubic Feet per Minute”)	250-725 CFM (“Cubic Feet per Minute”)	Similar, the subject device has higher flows in worst case condition

SUMMARY OF NON-CLINICAL TESTING:

Shown below is the performance testing performed with the subject device to demonstrate the device can meet the acceptance criteria of the test methodology and standard.

Name of Test Methodology	Purpose	Acceptance Criteria	Results
Microorganism Reduction Testing	Demonstrate reduction of representative organisms in single-pass testing	Greater than 99.9% reduction in single-pass testing	Demonstrated effectiveness against MS2 virus, B. atropheus, S. epidermidis.

UL 507: 2017 Ed. 10	PASS
IEC 60601-1-2 Ed. 4.0	PASS
Particulate Reduction Testing	SIMILAR TO PREDICATE

CONCLUSION:

The conclusions drawn from the nonclinical tests demonstrate that the Aerocure-MD device is as safe, as effective, and performs as well as or better than legally marketed predicate device.