September 18, 2023

Medify Air LLC
Pragati Anand
VP, Ecommerce & Omnichannel
150 E Palmetto Park Rd, Suite 301
Boca Raton, Florida 33432

Re: K223835
Trade/Device Name: MA-40, MA-112
Regulation Number: 21 CFR 880.5045
Regulation Name: Medical Recirculating Air Cleaner
Regulatory Class: Class II
Product Code: FRF
Dated: July 28, 2023
Received: August 2, 2023

Dear Pragati Anand:

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,

Christopher K. Dugard -S

Christopher K. Dugard, M.S.
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)*

K223835

Device Name
MA-40, MA-112

Indications for Use *(Describe)*

The MA-40 and MA-112 are intended for use as room recirculating air cleaner. The systems are used for filtering out and inactivating airborne particles from the air for medical purposes.

The MA-40 has been demonstrated to reduce the following airborne microorganisms by >99.99% in a test chamber of 83ft^3 (580 ft^3)

BIOAEROSOL TYPE	SPECIES	DEVICE FAN SPEED	TOTAL TRIAL TIME (MINUTES)
Virus	MS2 bacteriophage	Speed 3	30
		Speed 2	45
		Speed 1	90
Virus	Phi-X 174 bacteriophage	Speed 3	30
Bacterial	Staphylococcus Epidermidis	Speed 3	30
Bacterial	Escherichia coli	Speed 3	30
Bacterial	Bacillus Subtilis Endospore	Speed 3	30
		Speed 2	45
		Speed 1	120
Mold	Aspergillus Brasiliensis	Speed 3	30

The MA-112 has been demonstrated to reduce the following airborne microorganisms by >99.99% in a test chamber of 83ft^3 (580 ft^3)

BIOAEROSOL TYPE	SPECIES	DEVICE FAN SPEED	TOTAL TRIAL TIME (MINUTES)
Virus	MS2 bacteriophage	Speed 4	20
		Speed 3	20
		Speed 2	30
		Speed 1	45
Virus	Phi-X 174 bacteriophage	Speed 4	20
Bacterial	Staphylococcus Epidermidis	Speed 4	20
Bacterial	Escherichia coli	Speed 4	20
Bacterial	Bacillus Subtilis Endospore	Speed 4	20
		Speed 3	20
		Speed 2	30
		Speed 1	45
Mold	Aspergillus Brasiliensis	Speed 4	20

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."