Dear Smart Air,

Thank you for contacting the Division of Industry and Consumer Education (DICE) at FDA's Center for Devices and Radiological Health (CDRH) DICE@fda.hhs.gov e-mail account.

To obtain information on a specific device, you may conduct a search via several publicly available databases. For instance, the Establishment Registration & Device Listing database provides information on firms that are actively registered with the FDA, including the name of the firm and a listing of the products that they manufacture and/or distribute. Additionally, the 510(k) Premarket Notification database and the Premarket Approval (PMA) database provide the ability to search for products that have been cleared or approved, respectively (see below explanation of these terms). Information is also available via the De Novodatabase, the Humanitarian Device Exemption (HDE) database, and the CLIAdatabase. These databases provide hyperlinks to documents that provide various information on the device, including descriptions of the device, how it functions, and when it was cleared or approved. For additional summary information, please feel free to refer to the Device Approvals, Denials and Clearances webpage and associated hyperlinks.

510(k):

For information regarding 510(k) cleared medical devices, please feel free to refer to the 510(k) Premarket Notification database. The database contains an historical record of cleared medical devices. You may conduct a search using any one, or several, of the fields provided in the database. For instance, you may search for all devices that have been cleared for a given "Product Code", or you may search for all devices that have been cleared for a given manufacturer (by entering the name of the manufacturer in the "Applicant Name" field).

Once you have conducted your search and have been taken to a search results page, you may click on any record for more detailed information about that particular clearance. The record typically includes a hyperlink to the 510(k) Summary or 510(k) Statement, including the SE letter and the Indications for Use page.

If you wish further information for a particular 510(k) submission, you may submit a Freedom of Information Act (FOIA)

Air purifiers that are not promoted for specific medical uses nor make claims that it prevents the spread of particular diseases, are not regulated by FDA as a medical device.

If the manufacturer wishes to label the device for indications to prevent or treat a specific respiratory disease, the device is Class II and requires 510(k):

Sec. 880.5045 Medical recirculating air cleaner. Product codes FRF Cleaner, Air Medical Recirculating

(a)Identification. A medical recirculating air cleaner is a device used to remove particles from the air for medical purposes. The device may function by electrostatic precipitation or filtration.

(b)Classification. Class II (performance standards).

If we can be of further assistance, please don't hesitate to contact us (Division of Industry and Consumer Education, DICE). We are available via email at DICE@fda.hhs.gov and also by phone at (800) 638-2041 (please refer to our webpage for our hours of operation). Please direct all new email inquiries to the main email address provided. Thank you.

Sincerely

Industry Team

Division of Industry and Consumer Education

Office of Communication and Education

Center for Devices and Radiological Health

U.S. Food and Drug Administration