



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Care-Tech Industries, Incorporated
c/o Mr. John O. Shannon, IES, IEE
CEO
8976 Seminole Blvd.
Seminole, Florida 33772

JUL - 6 2005

Re: C050111
Device Name: Odatus Air Purifier
Dated: May 9, 2005
Received: May 13, 2005

Dear Mr. Shannon:

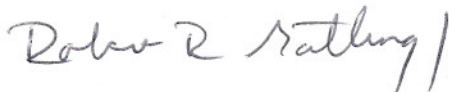
We have reviewed the above referenced request for information, submitted in accordance with Section 513(g) of the Federal Food, Drug, and Cosmetic Act (Act), regarding the regulatory requirements applicable to the Odatus Air Purifier. Based on the information provided in your submission, we believe that the Odatus Air Purifier falls within Title 21 of the Code of Federal Regulations (CFR) 880.5045, Medical recirculating air cleaner. A medical recirculating air cleaner is a Class II type device. Therefore you will need to submit a premarket notification [510(k)] and receive the Food and Drug Administration's (FDA's) clearance prior to marketing your device. You may not market this device until you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Act.

Please be advised that Title 21 Code of Federal Regulations, Part 807.40 requires that all foreign establishments that are engaged in the manufacture, preparation, propagation, compounding, or processing of a device that is offered for import into the U.S. are required to register and list with the FDA. If you have any questions regarding the registration and listing requirements, please call 240-276-0132.

Section 513(g) of the Act requires the agency to provide information about the regulatory requirements applicable to a particular type of device. The response represents my best judgment about how the product would be regulated, based upon our review of the information you have provided, including your description of the product and its intended use. My response to a 513(g) request is not a classification decision for a device and does not constitute FDA clearance or approval for commercial distribution.

If you have any questions regarding this letter, please contact Sheila Murphey, M.D., Chief, Infection Control Devices Branch, at (301) 594-1287, or for general questions please contact the Division of Small Manufacturers International and Consumer Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



for

Donna-Bea Tillman, Ph. D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health