MAR 2 7 2008

K072185

510(k) SUMMARY

Airistar Technologies, L.L.C.
2330 Ernie Krueger Circle
Waukegan, IL 60087
847-775-8018
847-775-8019 (fax)
800-755-8006 (toll-free)
info@airistar.com

Traditional 510(k) Premarket Submission

Contact: Roy Kibbe, President

Date prepared: March 12, 2008

Common Name: **Air Filtration Systems – Air Cleaners – Air Purifiers**
Proprietary Name: **Airistar Air Purification System (Model 500 & Model 1000)**

Classification:

Regulation # 880.5045; Class 2
Product Code FRF

Description: The Airistar Air Purification Systems - Model 500 & Model 1000 are medical air cleaners designed to help remove particulate matter from the air. These systems are for home use and use in hospitals, nursing homes, schools, offices, etc.

The Model 500 Airistar Air Purification System contains software and a display panel to program runs times and fan speeds, the panel also displays filter life indicator bar. The Model 1000 Airistar Air Purification System is operated via a power switch and control knobs to adjust the fan speed. Both models have 3 fan speeds and contain a 6 Stage filter system.

Intended Use: Airistar Air Purification Systems (Model 500 & Model 1000) are intended for use in filtering airborne particles from air for medical purposes.

Predicate Devices: The Airistar Air Purification System is substantially equivalent to the following predicate devices.

Hepa-Care Air Cleaner, Model HC400F & HC400E-UV by Abatement Technologies, Inc.
510(k) #: K984116

MOBILE PARTICULATE CONTAMINATION CONTROL SYSTEM, Airex, Inc.
510(k) #: K023693

Advanced Air Cleaner System, Healthway Products,
510(k) #: K012549

Safety and Effectiveness and Summary and Conclusion Regarding Substantial Equivalence:

By definition, a device is substantially equivalent when the device has the same intended use and the same technological characteristics as the predicate device, or has the same intended use and different technological characteristics, but it can be demonstrated that the device is as safe and effective as the predicate device and the new device does not raise different questions regarding safety and effectiveness as compared to the predicate device.

The minor differences between the Airistar Air Purification Systems (Model 500 & Model 1000) and the predicate devices cited do not raise any additional questions regarding safety and effectiveness. The intended use of the Airistar Air Purification Systems (Model 500 & Model 1000) is the same as the intended use of the predicate devices.

The device, as designed, is as safe and effective as the predicate device, and the device is determined to be substantially equivalent to the referenced predicate device.

Bench testing has confirmed the devices' ability to remove particles efficiently. The filters have been tested and listed by Underwriters Laboratories. Laboratory testing showed the UV lamp produced zero ozone.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Airistar Technologies LLC
C/O Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
Buffalo, Minnesota 55313

MAR 2 7 2008

Re: K072185
Trade/Device Name: Airistar Air Purification Systems – Model 500 & Model 1000
Regulation Number: 21 CFR 880.5045
Regulation Name: Medical Recirculating Air Cleaner
Regulatory Class: II
Product Code: FRF
Dated: March 13, 2008
Received: March 14, 2008

Dear Mr. Job:

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. 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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from 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,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K 072185

Device Name: Airistar Air Purification Systems – Model 500 & Model 1000

Indications For Use: Intended for use in filtering airborne particles from air for medical purposes.

Prescription Use _____ AND/OR Over-The-Counter Use __X____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K 072 185