K 033448

JUL 1 2 2004

510(k) SUMMARY

Air Purifier 3707 UVC

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with the Safe Medical Device Act of 1990 revisions to 21 CFR, Part 807.92, Content and Format of 1 510Kk) Summary.

1. **Submitted By:**

Dr. John Yuen
John Manufacturing Ltd.,
G/F., Yau Lee Center, 45 Hoi Yuen Road,
Kwun Tong, Hong Kong
China

2. **Contact Person:**

Dr. Arthur King Ma, JD DBA
A GROUP
18780 Amar Road, STE 202-203
Walnut, CA 91789
Tel: 1-626-581-1290 Fax: 1-626-581-1291
Cell: 1-626-786-0075

3. **Date Prepared:**

October 27, 2003

Date Revised:
April 02, 2004
June 2, 2004

4. **Proprietary Name:**

Air Purifier 3707 UVC

5. **Common/Usual Name:**

Air Purifier

6. **Classification Name:**

§ 880.6500 Medical Ultraviolet Air Purifier. A device designed to remove particles from air, as class II devices, product code FRA, and it is reviewed by General Hospital Devices.

7. **Predicate Device:**

AiroCide TiO2 (K023830)

8. **Device Description**

Air Purifier 3707 UVC device is an adjustable and portable personal system for treating air in a specified area of a room. **Air Purifier 3707 UVC** device contains an air treatment system, including a housing unit with an air inlet and a treated air outlet, a blower and a filter for removing contaminants from the air flowing along the flow path. **Air Purifier 3707 UVC** device contains also an air filtering system with an Ultraviolet radiation tube which purified air.

9. Intended Use:

The **air purifier 3707 UVC** is used to reduce airborne particles, such as: dust, smoke, pollen, mold spores, animal hair, dust mites that may cause allergy in rooms or enclosed areas such as treatment rooms, hospital wards, intensive care hospital wards and residential homes.

10. Performance Standards:

No performance standards have been established for such devices under Sections 514 of the Federal Food, Drug and Cosmetic Act. However, the **Air Purifier 3707 UVC** complies with the Standard for Electrostatic Air Cleaners, UL 867 and the Canadian Standard for Electrostatic Air Cleaners, CSA C22.2 No. 187-M1986.

11. Substantial Equivalence:

The **Air Purifier 3707 UVC** is substantial equivalence to AiroCide TiO2 (K023830) in respect to intended use, characteristics and device descriptions.

End of 510(k) Summary

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 1 2 2004

John Manufacturing Limited
C/O Mr. Arthur King Ma
A GROUP, Incorporated
18780 Amar Road Suite 202-203
Walnut, California 91789

Re: K033448
Trade/Device Name: Air Purifier 3707 UVC
Regulation Number: 880.6500
Regulation Name: Medical Ultraviolet Air Purifier
Regulatory Class: II
Product Code: FRA, FRF
Dated: June 29, 2004
Received: June 29, 2004

Dear Mr. King Ma:

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.

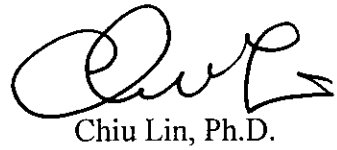
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (301) 594-4618. 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/dsma/dsmamain.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): K033448

Device Name: **Air Purifier 3707 UVC**

The **air purifier 3707 UVC** is used to reduce airborne particles, such as: dust, smoke, pollen, mold spores, animal hair, dust mites that may cause allergy in rooms or enclosed areas such as treatment rooms, hospital wards, intensive care hospital wards and residential homes.

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

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEED

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K033448