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510(K) Summary K070722

Summary of Safety and Effectiveness

DEC 1 4 2007

Submitted By: **Laurent Descôtes**

Date Prepared: **11 December**, 2007

Trade/Proprietary Name: Plasmair™ *Model T2006*

Common/Usual Name: Air Filtration System; HEPA Air Filtration System

Classification Name: Medical recirculating air cleaner. (per 21 CFR 880.5045)

Classification: FDA has classified these devices in Class II.

Panel: 80 Product Code: FRF

Purpose of Submission

The purpose of this submission is to establish the substantial equivalence of a new device not previously marketed in the USA (Plasmair™ *Model T2006*) to devices previously cleared through the 510(k) process.

Substantial Equivalence

The new device is substantially equivalent to the Biological Controls, Inc, MICROCON 800MUV (K972064).

Technological Characteristics

The device uses spatially modulated, amplified multidirectional electrostatic field technology to create cold plasmas for decontamination and capture of airborne particulates. These technologies do not raise new questions of Safety or Effectiveness.

Performance Data

Electrical safety and performance data included in the submission established that the device meets the performance specifications.

Conclusion

Airinspace, BV concludes based on the information presented that the Plasmair™ *Model T2006* is substantially equivalent to the current legally marketed products in the USA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 4 2007

AirInSpace B.V.
C/O Mr. Wade Tetsuka
Consultant
Wade Tetsuka
43795 Lee Mill Square
Leesburg, Virginia 20176

Re: K070722
Trade/Device Name: Plasmair™ Model T2006
Regulation Number: 21 CFR 880.5045
Regulation Name: Medical Recirculating Air Cleaner
Regulatory Class: II
Product Code: FRF
Dated: November 21, 2007
Received: November 29, 2007

Dear Mr. Tetsuka:

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.

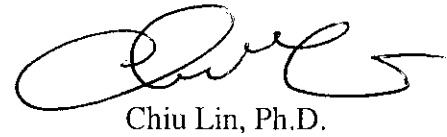
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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: **K070722**

Device Name: Plasmair™ *Model T2006*

Indications for Use: The Plasmair *Model T2006* is intended as a room air purifier/recirculating air cleaner. The system is used for filtering out and inactivating airborne particles from the air for medical purposes. The Plasmair *T2006* is designed to treat indoor air to supplement existing building air treatment and/or provide air treatment where none exists.

Concurrence of CDRH, Office of Device Evaluation (ODE)

K070722

Prescription Use: _____ **or** **Over-the-Counter Use:** __X___
(Per 21 CFR 801.109)