K052087

510(k) SUMMARY

DEC 14 2005

Submission Correspondent: Emergo Group, Inc.
Address: 2454 McMullen Booth Road
Suite 427
Clearwater, FL 33759
Phone: (727) 797-4727
Fax: (727) 797-4757

Contact: Mr. Ian Gordon

Submission Sponsor: AG Industries
239 Seebold Spur
Fenton, MO 63026

Date Prepared: October 17, 2005

Trade Name: Breathing Filter Bacterial / Viral

Common Name: Bacteria Filter

Classification: CAH, Filter, Bacterial, Breathing-Circuit
Regulation # 868.5260

Description: The Breathing Filter is a replacement filter for use mechanical ventilators, anesthesia machines, manual resuscitation devices, and IPPB machines. The product is composed of 3 main elements. These include a top housing, a bottom housing, and a filter element. The filter material is secured in the top and bottom housing using a sonic weld joint.

- The top housing is made of plastic and has a clear polish finish and has a standard 22mm ID connection port.
- The bottom housing is made of plastic and has a clear polish finish and has a standard 15mm ID/22mm OD connection port for universal usage.
- The filter element is composed of electrostatic material, with a bonded scrim, on one side of the filter element only.

Intended Use: The AG Industries Breathing Filter Bacterial/Viral is a single use replacement filter intended for use in mechanical ventilators, anesthesia machines, manual resuscitation devices, and IPPB machines to reduce the passage of particulate that may carry airborne bacteria and/or viruses. When used with mechanical ventilators, IPPB machines and resuscitation devices, the replacement filter may be used in the hospital, home, or transport applications.

Predicate Devices: The predicate device referenced in this submission is:

Hudson Respiratory Care, Inc. – Hudson RCI Bacteria/Viral Filter - 510(k) # K961914

Safety and Effectiveness:

Performance testing has been completed on the AG Industries Breathing Filter Bacterial/Viral. The differences between the AG Industries Breathing Filter Bacterial/Viral specifications and the predicate device specifications do not result in different performance or raise new questions regarding safety and effectiveness.

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 differences between the AG Industries Breathing Filter Bacterial/Viral and the predicate device cited do not raise any different questions regarding safety and effectiveness. There are no significant differences in the technological characteristics or in the intended use of these devices.

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 14 2005

AG Industries
C/O Mr. Ian Gordon
Emergo Group, Incorporated
2454 McMullen Booth Road
Clearwater, Florida 33759

Re: K052087
Trade/Device Name: Breathing Filter Bacterial/Viral
Regulation Number: 21 CFR 868.5260
Regulation Name: Breathing Circuit Bacterial Filter
Regulatory Class: II
Product Code: CAH
Dated: December 5, 2005
Received: December 12, 2005

Dear Mr. Gordon:

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.

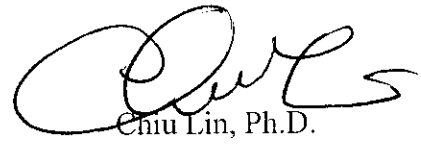
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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) 276-0120. 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): K052087

Device Name: **Breathing Filter Bacterial / Viral**

Indications for Use:

The AG Industries Breathing Filter Bacterial/Viral is a single use replacement filter intended for use in mechanical ventilators, anesthesia machines, manual resuscitation devices, and IPPB machines to reduce the passage of particulate that may carry airborne bacteria and/or viruses. When used with mechanical ventilators, IPPB machines and resuscitation devices, the replacement filter may be used in the hospital, home, or transport applications.

Prescription Use X AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Division Sign-Off
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number K052087