JUN 2 3 2005

K050424

EXHIBIT 2

510(k) Summary

FIM Medical

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February 10, 2005
Contact: Eric Derei, President

1. **Identification of the Device:**
   Proprietary-Trade Name: Ergofilter™ SP1 Accessory to Spirolyser SPL-50
   Classification Names: Spirometer, diagnostic BZG or Filter, Bacterial, Breathing Circuit, Product Code CAH
   Common/Usual Name: Filter (accessory to spirometer)

2. **Equivalent legally marketed devices** PULMOGUARD DISPOSABLE BATERIAL/VIRAL FILTER, K934509

3. **Indications for Use (intended use)** The accessory is a Bacterial/Viral Filter designed for single patient use. For use on both adult and pediatric patients.

4. **Description of the Device:** The Ergofilter™ SP1 filter is a bacterial and viral filter with an anatomical mouthpiece, for spirometers. The filter is a single use, non-sterile filter. A new filter must be used for each new patient and for each new spirometry examination. Operating principle of Filtrete™ 3M™ filtration medium: The filtering medium is manufactured by the 3M company in a clean room; it uses an electrostatic process which attracts small mass particles, while having a very small resistance to air flow; the density and thickness of the filtration medium itself provides an increased filtration capacity.

5. **Safety and Effectiveness, comparison to predicate device.** The results of bench and clinical testing indicates that the new device is as safe and effective as the predicate devices.

6. **Comparison to predicate**:

Characteristic	PULMOGUARD DISPOSABLE BATERIAL/VIRAL FILTER K934509	Ergofilter™ SP1
Indications for Use	Intended to reduce cross-contamination between the patient and the spirometers and pulmonary function testing instruments. Single patient use.	SAME
Intended population	Any patient	SAME
Intended environment	Hospital, outpatient, home	SAME
Design features		
Compact housing	Yes	SAME
Various end fittings	Yes	SAME
Filter medium	3 M electrostatic filtration medium, polypropylene	SAME
Enclosure material	Plastic	Food contact grade, meets 21CFR177.1520.
Single patient, non-sterile	Yes	SAME
Prescription device	Yes	SAME
Airflow resistance	0.862cm H_20/L/Sec at 14L/Sec	0.60cmH_2O/L/s at 12 L/Sec
Dead volume	60 ml	65 ml
% of bacterial removal efficiency	>99.7%	>99.9 %
Compatibility	Fits Most Adult Spirometers without an Adapter. Adapters Available	SAME
Performance standard	NONE	NONE

7. **Conclusion**

After analyzing bench, filter effectiveness, and clinical testing data, it is the conclusion of FIM Medical that the Ergofilter™ SP1 Accessory to Spirolyser SPL-50 as safe and effective as the predicate devices, has few technological differences, and has no new indications for use, thus rendering it substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 3 2005

FIM Medical
C/O Mr. Daniel Kamm, P.E.
Kamm & Associates
P.O. Box 7007
Deerfield, Illinois 60015

Re: K050424
Trade/Device Name: Ergofilter™ SP1 (Accessory to Spirolyser SPL-50)
Regulation Number: 21 CFR 868.1840
Regulation Name: Diagnostic Spirometer
Regulatory Class: II
Product Code: BZG
Dated: May 2, 2005
Received: May 10, 2005

Dear Mr. Kamm:

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): K050424

Device Name: Ergofilter™ SP1 (Accessory to Spirolyser SPL-50)

Indications For Use:
Intended to perform spirometry and may be used in hospitals and medical offices or at other locations including homes. The accessory is a Bacterial/Viral Filter designed for single patient use. For use on both adult and pediatric patients.

Prescription Use X AND/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 NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K050424