DEC - 1 2003

K031102

Non-Confidential Summary of Safety and Effectiveness
April 4, 2003

Micro Direct, Inc.
803 Webster Street
Lewiston, ME 04240

Tel - (207) 786-7808 Fax - (207) 786-7280

Official contact: David R. Staszak, President

Proprietary or Trade Name: Microlab Spirometer

Common/Usual Name: Spirometer

Classification Name: 73 BZG – Diagnostic Spirometer

Intended device: Diagnostic Spirometer

Predicate devices: Micro Medical MicroDL Diarycard Spirometer

Device description: The Microlab spirometry systems consists of the Microlab spirometer, digital volume transducer, transducer housing, AC power adapter, power supply cord, disposable cardboard mouthpieces, carrying case, quick start guide and operators manual. Optional accessories include calibration syringe, nose clips, serial cable and a serial to parallel converter for use of an external compatible printer.

Intended use: The Microlab spirometry system is intended, for prescription use only, to measure the maximal volume and flow of air that can be moved in and out of a patient's lungs. The testing can be used in the detection and monitoring of certain lung diseases. The system is intended for use with pediatric and adult patients (4 to 99 years old) in hospitals, physician offices, laboratories and occupational health testing environments.

Comparison to predicate device: The Microlab spirometry system has the same technological characteristics of the referenced predicate device. In both devices, air flow is measured directly via a turbine sensor and then electronically integrated to obtain volume. Both devices then perform calculations to express the volume in clinically relevant terms, including comparisons to predicted normal values from published literature. The intended use for both devices is the same.

Summary of Testing: Performance testing was conducted to demonstrate compliance with the accuracy and precision standards set by the American Thoracic Society.

The device was tested to demonstrate conformance with IEC60601-1-2 requirements for electrical safety.

Conclusion: The Microlab spirometry systems does not raise new questions of safety or effectiveness when compared to the legally marketed predicate device and is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 1 2003

Mr. David R. Staszak
President
Micro Direct, Incorporated
803 Webster Street
Lewiston, Maine 04240

Re: K031102
Trade/Device Name: Microlab Spirometer
Regulation Number: 21 CFR 868.1840
Regulation Name: Spirometer, Diagnostic
Regulatory Class: II
Product Code: BZG
Dated: September 24, 2003
Received: September 25, 2003

Dear Mr. Staszak:

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.

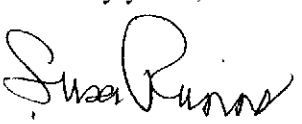
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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) 594-4646. 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 Statement

510(k) Number K031102 (To be assigned)

Device Name: Microlab Spirometer

Indications for Use: The Microlab spirometer is intended, for prescription use only, to measure the maximal volume and flow of air that can be moved in and out of a patient's lungs. The system is intended for use with pediatric (4 to 17 years) and adult (18 to 99 years) patients in hospitals, physician offices, laboratories and occupational health testing environments.

Concurrence of CDRH, Office of Device Evaluation (ODE)

for JXH 11/25/03

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

510(k) Number: K031102

Prescription Use ✓ OR Over-The-Counter Use ___
(Per 21 CFR 801.109)