K030586

AUG 27 2003

Micro Direct

Non-Confidential Summary of Safety and Effectiveness
February 18, 2003

Micro Direct, Inc.
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Lewiston, ME 04240

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Official contact: David R. Staszak, President

Proprietary or Trade Name: MicroPeak

Common/Usual Name: Peak Flow Meter

Classification Name: BZH – Meter, Peak Flow

Intended device: Peak Flow Meter

Predicate devices: Vitalograph Asmaplan+ - K781922

Device description: A peak flow meter is a device used to measure a person's peak expiratory flow rate.

Indicated use:

The intended device measures a patient's peak expiratory flow rate.

Targeted population:

Patients requiring the measurement of peak expiratory flow.

Environment of use:

Anywhere that a patient may require the measurement of peak expiratory flow.

Comparison to predicate devices:

Attribute	**Intended device**	**Vitalograph Asmaplan+**
Use		
Intended as a peak flow meter	Yes	Yes
Intended to measure peak expiratory flow	Yes	Yes
Design		
Single patient Use	Yes	Yes

Comparison to predicate devices (continued)

Attribute	Intended device	Vitalograph Asmaplan+
Materials		
Housing – ABS	Yes	Yes
Measuring Principle	Tension Spring Piston/Pointer	Tension Spring Piston/Pointer
Performance		
Range	60 - 900 L/Min	50 – 800 L/M
Accuracy	+/- 10%	+/- 10%
Intra device Precision	+/- 5%	+/- 5%
Inter device Precision	+/- 5%	+/- 5%

Differences
The only difference is a small difference in the measurement range.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 27 2003

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

Re: K030586
Trade/Device Name: MicroPeak
Regulation Number: 21 CFR 868.1860
Regulation Name: Peak Flow Meter for Spirometry
Regulatory Class: II
Product Code: 73 BZH
Dated: May 30, 2003
Received: June 3, 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,

Susan Runner

Susan Runner, DDS, MA
Interim 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 K030586 (To be assigned)

Device Name:	MicroPeak Peak Flow Meter
Indications for Use:	The intended device simply measures a patient's peak expiratory flow rate in liters/minute. This is helpful in monitoring respiratory conditions such as asthma.
Targeted population:	Patients requiring the measurement of peak expiratory flow rate.
Environment of use:	Places where a patient may require the measurement of their peak expiratory flow rate.

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K030586

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