K960542

JUN 17 1997

Non-Confidential Summary of Safety and Effectiveness
December 15, 1996

Micro Direct, Inc.
840 Pownal Road
Auburn, ME 04210

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Official contact: David R. Staszak, President

Proprietary or Trade Name: MicroDL DiaryCard Spirometer

Common/Usual Name: Diagnostic Spirometer

Classification Name: 73 BZG - Diagnostic Spirometer

Intended device: Diagnostic Spirometer

Predicate devices: Micro Medical Micro Spirometer - K963035

Device description: A hand-held portable electronic spirometer measuring FEV1, FVC, and PEF.

Indicated use:

The intended device takes spirometer readings of a patient during exhalation. The output readings are FEV1, FVC, and PEF.

Targeted population:

Patients requiring lung function evaluations.

Environment of use:

Places where a qualified clinician desires to take these lung measurements - FEV1, FVC, and PEF.

Comparison to predicate devices:

Attribute	**Intended device**	**Micro Medical Micro Spirometer**
Use Intended as a spirometer	Yes	Yes
Intended to measure lung function FEV1, FVC, and PEF	Yes	FEV1 and FVC

Comparison to predicate devices (continued)

Attribute	**Intended device**	**Micro Medical Micro Spirometer**
Use (continued)		
Indicated for measuring patients lung function	Yes	Yes
Indicated for use by a clinician in environments such as the home or hospital	Yes	Yes
Manufactured by Micro Medical	Yes	Yes
Design		
Transducer - flow sensing turbine	Yes	Yes
Output	RS232	No
Flow range LPs BTPS 0-12	Yes	Yes
Volume range liters 0-9.99	Yes	Yes
Test Parameters	FEV1, FVC, PEF	FEV1, FVC
Accuracy +/- 3	Yes	Yes
Display LCD	Yes	Yes
Transducer cleaned after use	Yes	Yes
Utilizes paper mouthpiece	Yes	Yes
Materials		
Same materials as K963035	Yes	Yes
Performance Testing		
None applicable	Yes	Yes

Differences
The only differences are the addition of the displayed test parameter of PEF (Peak Expired Flow) and the ability to retain the test values in memory for later review.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 17 1997

Mr. David R. Staszak
Micro Direct, Inc.
840 Pownal Road
P.O. Box 239
Auburn, Maine 04212-0239

Re: K965042
MicroDL DiaryCard Spirometer
Regulatory Class: II (two)
Product Code: 73 BZG
Dated: March 17, 1997
Received: March 19, 1997

Dear Mr. Staszak:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number K965042 (To be assigned)

Device Name:	MicroDL DiaryCard Spirometer
Indications for Use:	To measure lung functions - FEV_1, FVC, and PEF and to effect historical serial transfer of measured test indices to PC compatible computers
Targeted population:	Patients requiring lung function measurements
Environment of use:	Places where a qualified clinician desires to take these lung measurements - FEV_1, FVC, and PEF.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark Mador 6-12-97

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K965042

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