DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 5 2004

Microlife Intellectual Property GmbH
C/O Ms. Susan D. Goldstein-Falk
Official Correspondent
MDI Consultants, Incorporated
55 Northern Boulevard, Suite 200
Great Neck, New York 11021

Re: K040723
Trade/Device Name: Microlife Electronic Peak Flow Meter with PEF and FEV1, Models PF-100 and PF-100-1 (with software)
Regulation Number: 868.1860
Regulation Name: Peak Flow Meter for Spirometry
Regulatory Class: II
Product Code: BZH
Dated: March 19, 2004
Received: March 23, 2004

Dear Ms. Goldstein-Falk:

This letter corrects our substantially equivalent letter of June 10, 2004, regarding the correction of OTC designation from prescription designation and correction of the indications for use statement to read "This device is intended for monitoring PEF (Peak expired flow rate) and FEV1 (forced expiratory volume in one second) for patient home use. The device is designed for pediatric to adult use."

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

**Attachment #1**



**510(k) Number (if known):** K040723

**Device Name:** Microlife Electronic Peak Flow Monitor, with PEF and FEV1, Models PF-100 and PF-100-1 (with Software)

**Indications For Use:**

This device is intended for monitoring PEF (Peak Expired Flow Rate) and FEV1 (Forced Expiratory Volume in one second) for patient home use. The device is designed for pediatric to adult patients.

**Prescription Use** _____ **OR** **Over-The Counter Use** _X_
**(Per 21 CFR 801 Subpart D)** **(21 CFT 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: K040723

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**EXHIBIT # 1**

K040723

## 510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: _____

### 1. Submitter's Identification:

Microlife Intellectual Property GmbH
Max Schmidheiny- Strasse 201
9435 Heerbrugg
Switzerland
Contact: Mr. Gerhard Frick

Date Summary Prepared: March 19, 2004

### 2. Name of the Device:

Microlife Electronic Peak Flow Monitor, with PEF and FEV1, Models PF-100 and PF-100-1 (with software)

### 3. Predicate Device Information:

Microlife Peak Flow Meter, Model PF100, K#031024, Microlife Intellectual Property GmbH

Accutrax Electronic Peak Flow Meter, Model EPF840, Korr Medical Technologies, Inc., Salt Lake City, Utah, K#982995

### 4. Device Description:

The Microlife Electronic Peak Flow Monitor, Model PF-100, comprises a hand held microprocessor based unit, incorporating a removable micro medical digital volume transducer. The transducer consists of an acrylic tube with a freely rotating vane supported on jeweled bearings positioned between a fixed swirl plate and a cross bar. As air is passed through the transducer, a vortex is created by the swirl plate, which causes the low inertia vane to rotate. The rotation of the vane is detected by the interruption of an infrared beam which produces an electrical pulse train at the output of a phototransistor. The number of rotations is proportional to the volume of air passed through the turbine, and the rate of

rotation is proportional to the flow rate. With flow rate and correspondent time, FEV1 can be calculated.

5. **Intended Use:**

This device is intended for monitoring PEF (Peak Expired Flow Rate) and FEV1(forced exhalation in the first second) for patient home use. The device is designed for pediatric to adult patients.

6. **Comparison to Predicate Device:**

Both devices meet the American Thoracic Society (ATS) recommendations for Spirometry. The new PF-100 (subject device) measures PEF and FEV1 parameters; the predicate, model PF100, measures only PEF (Peak Expired Flow Rate). The new PF100 measuring principle is exactly the same as the one in PF100 determination of respiratory flow-infrared rotary flow sensor (meeting ATS accuracy testing using the 26 flow-time waveform and the 24 volume-time waveform).

The new PF100 is identical in functionality and performance with the only difference being the FEV1 measurement is added to the new device, and the PC connection is with USB port instead of RS232. Others like shape, material remain the same.

7. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

The subject device was tested to and passed the ATS Standard Waveforms using a waveform generator. Product Safety Testing included successful completion of testing to the IEC 60601-1 (electrical safety) and IEC 60601-1-2 (electromagnetic compatibility) standards.

8. **Discussion of Clinical Tests Performed:**

Not Applicable

## 9. Conclusions:

The subject device, Microlife Electronic Peak Flow Monitor, with PEF and FEV1, Models PF-100 and PF-100-1 (with software) has a similar intended use and similar characteristics as the predicate device. Moreover, bench tenting contained in our submission and non-clinical testing supplied demonstrates that there are no differences in their technological characteristics, thereby not raising any new questions of safety or effectiveness. Thus, Microlife Electronic Peak Flow Monitor, Model PF-100 is substantially equivalent to the predicate devices.