NOV 1 4 2003

EXHIBIT # 1

510(K) SUMMARY

This summary of 5l0(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA l990 and 21 CFR §807.92.

The assigned 5l0(k) number is: K031024

1. **Submitter's Identification:**

Microlife Corporation
9F, 431 Rui Guang Road
Nei Hu,
Taipei 114
Taiwan, Republic of China

Contact:

Mr. Gerhard Frick

Date Summary Prepared: March 27, 2003

2. **Name of the Device:**

Microlife Electronic Peak Flow Monitor, Model PF-100

3. **Predicate Device Information:**

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

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.

5. Intended Use:

This device is intended for monitoring PEF (Peak Expired Flow Rate) for patient home use. The device is designed for pediatric to adult patients. The simple device interface provides ease of use for pediatric patients. When the device is used to monitor lung conditions such as asthma, the user should be under the care of a licensed health care professional. A licensed health care professional's advice is required to understand the meaning and importance of the measurements reported by the device and how to decide on an appropriate treatment plan. This treatment plan will tell the patient what action to take when there are changes in their PEF measurements.

6. Comparison to Predicate Device:

Both devices meet the American Thoracic Society (ATS) recommendations for Spirometry. The PR-100 (subject device) measures only PEF parameter; the predicate measures both PEF (Peak Expired Flow Rate) and FEV_1 (Forced Expired Volume). The PF-100 measuring principle is determination of respiratory flow-infrared rotary flow sensor (meeting ATS accuracy testing using the 26 flow-time waveform), whereas the predicate device uses a pneumotach (flowhead) with fixed obstruction that generates a back pressure in response to the measured flow rate.

For flow measuring accuracy, the PF-100 is above the ATS Standard (+/-20 l/min). Regarding memory, the PF-100 automatically stores up to 120 measurements with time and date; the predicate device stores up to 480 sets. The PF–100 device is powered with 2 AAA Batteries – the predicate device is powered with a 9-Volt alkaline battery. Both device mouthpieces are made of ABS plastic. Both devices store the PEF values in non-volatile memory with a time and date stamp. Both devices are substantially equivalent.

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, Model PF-100 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.

11

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 4 2003

Microlife Corporation
C/O Ms. Susan Goldstein-Falk
MDI Consultants, Incorporated
55 Northern Boulevard
Suite 200
Great Neck, New York 11021

Re: K031024
Trade/Device Name: Microlife Electronic Peak Flow Monitor, Model PF-100
Regulation Number: 868.1860
Regulation Name: Spirometry Peak Flow Meter
Regulatory Class: II
Product Code: BZH
Dated: October 17, 2003
Received: October 20, 2003

Dear Ms. Goldstein-Falk:

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.

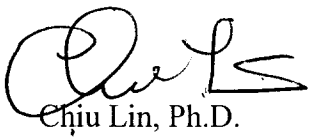
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

Exhibit B

510(k) Number (if known): K031024

Device Name: Microlife Electronic Peak Flow Monitor, Model PF-100

Indications For Use:

This device is intended for monitoring PEF (Peak Expired Flow Rate) for patient home use. The device is designed for pediatric to adult patients. The simple device interface provides ease of use for pediatric patients. When the device is used to monitor lung conditions such as asthma, the user should be under the care of a licensed health care professional. A licensed health care professional's advice is required to understand the meaning and importance of the measurements reported by the device and how to decide on an appropriate treatment plan. This treatment plan will tell the patient what action to take when there are changes in their PEF measurements.

(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: K031024