510(k) Number K013489 **Date** _____

510(k) Summary — KP+ LFM Flow Meter for Spirometry

Submitter:

Company:	PDS Healthcare Products, Inc. 908 Main Street, Louisville, Colorado 80027 303 666 6340, 303 666 6380 Fax
Contact:	Jim Lewis, Regulatory Associate
Prepared:	19 October 2001

Device Name:

Trade:	KP+ LFM
Common:	Flow meter for spirometry
Classification:	Peakflow meter for spirometry [21 CFR 868.1860]

Predicate Device:

Trade Name:	KoKo Peak KP+
510(k) Number:	K010009
Manufacturer:	PDS Healthcare Products, Inc.

Description of Device:

KP+ LFM is a model variation of the KoKo Peak KP and KP+ peak flow meters. The KoKo Peak KP+, complete with data-communication accessory and dedicated PC display software, was cleared for over-the-counter sale in 510(k) notification K010009. The LFM is identical to its predicate device—the KP+—physically, technologically, and logically.

This new variation extends some KP+ features—namely, an additional timed flow measurement and extended electronic features. These variations make the LFM a prescription device, rather than an over-the-counter one, like its predicate.

All KP flow meters are personal, electronic, flow meters for measuring the rate at which a person blows through them. Approximately 5x2x1 inches in size, the devices are battery-powered, hand-held, single-user instruments with a mouthpiece removable for cleaning. The meter has a custom liquid-crystal display, one-button operation, and an infrared data port for communicating to a serial port of a PC through an optional data-communication link.

Selecting between the models is done during manufacture by simply setting appropriate flags in the device's memory. This selection can be done during initial calibration at the factory, only. The model is then designated by packaging and labeling.

LFM features include

- Performing all KoKo Peak KP+ features and functions
- Measuring six-second forced expiratory volume (FEV6) by continuing to integrate the breath flow measurement over a 6-s period and displaying the value after a test session
- Displaying the FEV1/FEV6 ratio on meter's front panel after a test session

- Enabling diary logs to be expanded to up to 16 entries from the 5 entries preprogrammed into the KP+
- Enabling options for uploading diary ranges, zone ranges, reference PEF, data-clear command, and alarm-clock settings directly to meter's memory from a PC

Indications for Use:

For personal monitoring of expiratory-breath function at home under direction of a physician. It measures, logs, and reports events related to respiration and the spirometric values of peak expiratory flow (PEF), zone and percent of PEF compared to a reference value, timed forced expiratory volumes over 1 second (FEV1) and 6 seconds (FEV6), and the ration of FEV1/FEV6.

Summary of Technological Characteristics:

There are no technological differences between the LFM and its predicate device.

Summary of Non-Clinical Performance Data:

Since LFM and its predicate, KP+, are physically identical, they meet the same standards for safety of medical electrical equipment.

Both KP+ LFM and its predicate device meet or exceed each aspect of American Thoracic Society standard for spirometry[1] as it relates to monitoring devices. Testing to ATS standard was performed successfully in-house using industry-recognized automatic waveform generator built specifically for that purpose.

Summary of Clinical Performance Data:

Since the device is identical to its predicate device and the added features are simply enhancements or extensions of features already available on the predicate device, no clinical testing was necessary or performed.

Technical Specifications:

Meter

- Dimensions: 120 x 70 x 20 mm
- Weight: 85 g
- Operating Temperature: 10 to 38 °C
- Operating Humidity: 0 to 100 %RH, non-condensing
- Storage Temperature: -20 to 60 °C
- Display: Reflective liquid crystal, 21x40 mm
- Power: Two 1.5-volt silver-oxide batteries
- Battery Symbol: Low battery
- Battery Life: 1 year (3 test sessions per day)
- Memory Capacity: 64 test sessions (FIFO overflow)
- Data port: Infrared optical

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[1] American Thoracic Society. Standardization of spirometry: 1994 update. *Am J Respir Crit Care Med* 152:1107–36, 1995.

Data cradle

- Dimensions: 90 x 60 x 40 mm
- Weight: 50 g (without batteries)
- Operating Temperature: 10 to 38 °C
- Operating Humidity: 0 to 100 %RH, non-condensing
- Storage Temperature: -40 to 70 °C
- Power: Four AAA alkaline batteries
- Battery Life: 1 year
- Meter data port: Infrared optical
- PC data port: 3-conductor wire to RS232 9-pin connector
- Computer requirement: serial port available

PC software

- Computer requirements:
  Accessories: SVGA monitor and graphic card, or better, CD-ROM drive
  Operating system: Windows 95, 98, or NT
  Memory: 32 MB of RAM
  Processor speed: Pentium 120 MHz or faster processor
  Disk capacity: 500 MB of available space
- Program size: 33.2 MB
- Physical media: CD

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 9 2001

Mr. Jim Lewis
PDS Healthcare Products, Inc.
908 Main Street
Louisville, CO 80027

Re: K013489
KP+ LFM
Regulation Number: 868.1860
Regulation Name: Peak Flow Meter
Regulatory Class: Class II (two)
Product Code: BZH
Dated: October 19, 2001
Received: October 22, 2001

Dear Mr. Lewis:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K013489

Device Name: KP+ LFM

Indications for Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K013489

(Optional Format 3-10-98)

✓ Prescription Use