OCT 0 4 2002

510(k) Number K022276 **Date** _____

KoKoMate Office Spirometer
510(k) Summary

Submitter

Company:	Pulmonary Data Services, Inc. 908 Main Street, Louisville, Colorado 80027 USA Tel 303 666 5555, Fax 303 666 5588
Contact:	Jim Lewis
Prepared:	11 July 2002

Device Name

Trade:	KoKoMate
Common:	Office spirometer[1]
Classification:	Diagnostic spirometer, 21 CFR 868.1840; Class II
Product code:	73-BZG

Predicate Devices

Trade Name:	AccuTrax
510(k) Number:	K982995
Manufacturer:	PDS [under contract from Korr Medical Technologies]
Trade Name:	Spirovit SP-2
510(k) Number:	K992823
Manufacturer:	Schiller AG

Device Description

KoKoMate is a hand-held, self-contained spirometer[2] with disposable mouthpiece designed specifically to measure a few simple expiratory spirometry values in the primary-care setting for diagnostic and screening purposes. The meter features a 4-line by 16-character LCD display; four control buttons; a port to accept its mouthpiece/flow-tube; and an IR data-transfer port.

The device measures expiratory breath flow through its mouthpiece, which is designed for single use. For a maximal expiratory effort, the meter determines peak expiratory flow (PEF), one-second forced expiratory volume (FEV1), six-second forced expiratory volume (FEV6), and average forced expiratory flow from 25 – 75% of total volume (FEF25-75%). It reports these values plus the ratio of FEV1/FEV6 and an indication of how these values compare to recognized predicted values. In addition, the meter processes the signals from each expiratory

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[1] Ferguson GT, Enright PL, Buist AS, Higgins MW. Office spirometry for lung health assessment in adults: A consensus statement from the National Lung Health Education Program. *Chest* 117:1146-1161, 2000.

[2] American Thoracic Society. Standardization of spirometry: 1994 update. *Am J Respir Crit Care Med* 152:1107-1136, 1995.

maneuver to help determine the quality of the maneuver to aid the clinician or patient in determining whether the reported values are valid.

Along with the spirometer, the KoKoMate system can include one of two optional accessory products. These accessories act as data transfer conduits transferring data streams across optic and serial interfaces as they cradle the meter. One cradle is designed to couple the meter to a PC for data storage, printout, or analysis; the other links the meter directly to a printer for direct printout of a simple spirometry report.

Indications for Use

KoKoMate is a diagnostic spirometer for use in the primary-care setting to measure and report the following spirometric values: Peak Expiratory Flow (PEF), One-Second (FEV1) and Six-Second (FEV6) Forced Expiratory Volumes, Forced Expiratory Flow averaged from 25 – 75% of total volume (FEF25-75%), and the ratio of FEV1/FEV6.

Summary of Technological Characteristics

The KoKoMate measures flow by pneumotachometry (using differential pressure across a known restriction to indicate air flow). The flow path in the meter is a single-use element mounted in pneumatic communication with a durable, reusable handle. The handle contains sensors and associated electronics for interpretation, storage, display, and communication of flow data and test results. The handle houses the battery, pneumatic sensor, analog-to-digital converter, embedded microprocessor, control buttons, multiple-line alphanumeric display, and infrared data port.

Data communication between the meter and a PC or printer may be made through IR data ports on the meter and in one of the optional data-transfer accessories. Data transfer, storage, and display on a PC is done with an existing Windows-based spirometry program available from PDS. Control firmware embedded in the Printer/PC Cradle allows direct printing of the data stored in the meter in a simple report format.

Summary of Non-Clinical Performance Data

Safety

KoKoMate units were examined and bench tested by third-party examiners to demonstrate conformance to two recognized international consensus standards for safety of medical electrical equipment. The standards are EN 60601-1:1988 with amendments for general safety and EN 60601-1-2:1993 for electromagnetic compatibility.

Effectiveness

In-house and third-party testing, using an ATS-compatible automatic waveform generator, demonstrated that the measurement performance of the spirometer met or exceeded requirements published in the National Lung Health Education Program's consensus statement for office spirometry[1] and in the American Thoracic Society's standard for diagnostic spirometry[2].

Meter function was also tested using specialized most-probable-error flow waveforms to validate measurement-quality features. The measurement-quality study demonstrated that the KoKoMate can appropriately provide information regarding a subject's PEF, FEV1, FEV6, FEF25-75%, and FEV1/FEV6 measurements and can identify measurements of suspect quality appropriately.

Summary of Clinical Performance Data

Testing in a simulated primary-care setting demonstrated that patients and clinicians in that environment can safely and effectively use the KoKoMate under conditions of actual use and that the users guide, product physical design, and other human-factor characteristics of the KoKoMate system are appropriate for the product's intended use.

Equivalence to Predicate Devices

The KoKoMate's design is a direct design enhancement of the AccuTrax predicate: using the same technologies, design principles, and manufacturing approach; but extending its features and accuracy. The system is substantially equivalent to the Spirovit SP-2: using the same measurement principles; using similar construction, material, and energy source; and meeting the same performance characteristics. The differences are that KoKoMate has a simpler user interface and reports a reduced set of spirometry values compared to the Spirovit.

Technical Specifications

Meter

- Dimensions: 170x70x40 mm
- Weight: 230 g
- Operating temperature range: 17 °C to 38 °C
- Operating humidity: 0 to 80%, non-condensing
- Accuracy, precision Meets ATS diagnostic spirometry[2]
- Storage temperature: -20 °C to 60 °C
- Display: LCD Display, 4 line x 16 character
- Power: One 9 V alkaline battery
- Battery life: Approximately 500 tests (3 months of expected usage)
- Memory capacity: 8 sessions (including pre/post challenge)
- Data port: Infrared optical
- Case material Impact polystyrene
- Mouthpiece material ABS Cycolac

Cradle

- Dimensions: 200x150x60 mm
- Weight: 320 g
- Operating temperature range: 17 °C to 38 °C
- Operating humidity: 0 to 80%, non-condensing
- Storage temperature: -20 °C to 60 °C
- Power:
- PC cradle: Powered from serial port of PC
- Printer/PC cradle: 12 VDC via AC mains-power adapter
- Data port:
- Meter: Infrared optical
- Computer/printer: RS232 serial data port
- Case material Impact polystyrene

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 0 4 2002

Mr. Jim Lewis
Director of Operations
Pulmonary Data Services, Incorporated
908 Main Street
Louisville, Colorado 80027

Re: K022276
Trade/Device Name: KoKoMate Office Spirometer
Regulation Number: 868.1840
Regulation Name: Diagnostic Spirometer
Regulatory Class: II
Product Code: BZG
Dated: July 11, 2002
Received: July 15, 2002

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,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K022276

Device Name: **KoKoMate Office Spirometer**

Indications for Use:

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number: K022276

(Optional Format 3-10-98)