K051572

NOV 17 2005

510(k) SUMMARY

Pulmonary Data Services, Inc.'s KoKo LEGEND

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Ferraris Respiratory, Inc.
908 Main Street
Louisville, CO 80027

Phone: 303-666-5555 ext. 416
Facsimile: 303-664-0485

Contact Person: Donald Henton

Date Prepared: June 13, 2005

Common or Usual Name KoKo LEGEND (Diagnostic Spirometer)

Classification Name Spirometer, Diagnostic

Predicate Devices
Collins Eagle II System – K831779
KoKo Spirometer – K914272
KoKoMate Office Spirometer – K022276

Intended Use

The KoKo LEGEND is intended to be used for diagnostic use in the pulmonary function testing (PFT) with an intended use and indication for use as a configurable, non-invasive pulmonary function tester (PFT) testing system. The KoKo LEGEND is indicated for use in: pulmonary function testing.

Technological Characteristics and Substantial Equivalence

Dimensions	9.25"W x 10"D x 2.75"H (23.5 cm X 25.4 cm X 7.0 cm)
Weight	3.6 lbs. (1.6 Kg)
Electrical Requirements	110 - 240 VAC 50, 60 Hz, 2.5 Amps (Switching power supply included 12 VDC output)
Fuse Type and Rating	N/A
Operating Environment	Temperature, 10 to 40 ^{o}C (50 to 104 ^{o}F) Relative Humidity, 0% to 80% at temperatures to 31 ^{o}C
Storage and Transportation Environment	Temperature, -20 to 70 ^{o}C (-40 to 158 ^{o}F) Humidity, 10% to 90% (non-condensing)
Type of Pneumotach	Flexible Variable Orifice
Reproducibility	<+/- 0.5%
Resistance	<1 .5 cm H_2O/L/sec as tested with KoKo Moe filter
Accuracy	+/- 3% or 100 ml, whichever is greater
Flow Range	+/- 16 L/sec
Calibration Volume	3-liter calibration syringe
Hardware Options	
Computer interface	Ethernet or USB connection with KoKoPFT Spirometry Software 4.5 or higher, operating on Windows 2000 or XP
Printers	HP Color Inkjet
Tests Performed	Spirometry

Conformity to Recognized Standards

Electrical safety: UL 2601-1, EN 60601-1, IEC 60601-1-1, and CSA 22.2 No. 1
Emissions and Immunity: IEC 60601-1-2
Performance: *ATS American Thoracic Society Standardization of Spirometry 1994 Update, Am J Respir Crit Care Med Vol 152. (1995)*

Substantial Equivalence

The Ferraris Respiratory KoKo LEGEND has the same intended use and indications, principle of operation, technological characteristics, and is substantially equivalent in safety and effectiveness to the former marketed predicate devices with respect to its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 17 2005

Mr. Donald Henton
Director, Regulatory Affairs/Quality Assurance
Pulmonary Data Services, Incorporated
908 Main Street
Louisville, Colorado 80027

Re: K051572
Trade/Device Name: Koko Legend
Regulation Number: 868.1840
Regulation Name: Diagnostic Spirometer
Regulatory Class: II
Product Code: BZG
Dated: November 11, 2005
Received: November 14, 2005

Dear Mr. Henton :

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.

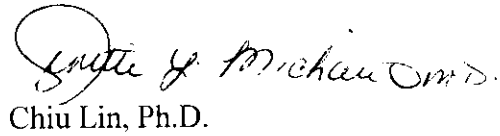
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-0115. 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/industry/support/index.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

Indications for Use

510(k) Number (if known): K051572

Device Name: Koko Legend

Indications for use: The KoKo LEGEND (Diagnostic Spirometer) is an Office Spirometer. It is intended as a configurable, portable, non-invasive pulmonary function tester (PFT) system. These tests are suitable for both pediatric and adult patient testing.

Prescription Use X (Part 21 CFR 801 Subpart D) **AND/OR** **Over-The-Counter Use** _____ (21 CFR 801 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: K051572