COSMED SRL., ITALY
COSMAD, Fitmate

K071533

Summary

SEP 2 8 2007

This device – Fitmate and Fitmate Pro both are is intended for use in clinical and research application to measure oxygen uptake. Fitmate and Fitmate Pro are designed for the measurement of Resting Metabolic Rate only. Fitmate Pro also measures maximal oxygen uptake (VO2max) that is used for assessing basic pulmonary function.

DESCRIPTION

Trade or proprietary name:	Fitmate series
Common or usual name:	Portable metabolic cart
Classification name:	Computer, Oxygen Uptake
Detailed Description:	Fitmate is designed for measuring oxygen uptake at rest and during exercise (VO_2max). The device is a metabolic monitor measuring Resting Metabolic Rate (RMR) and Exercise Capacity – VO_2max (maximal oxygen uptake), during a sub-maximal or maximal exercise protocol
Intended Use: and	Fitmate series family includes Fitmate Fitmate Pro. Fitmate is specifically designed for the measurement of Resting Metabolic Rate only, Fitmate Pro includes also the measurement of maximal oxygen uptake (VO_2max).

ESTABLISHMENT:

Registration Number:	8021084
Address:	COSMED SRL

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00040 Italy
Tel: +39-06-9315492,
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e-mail: info@cosmed.it

DEVICE CLASS UNDER SECTION 513:

Class:	II
Product Code:	BZL
Classification Panel:	AN

SUBSTANTIAL EQUIVALENT:

The COSMED Fitmate is similar to the Reevue Indirect Calorimeter, Model # 8100 (K021490) manufactured by Korr Medical Technologies, Inc., 3090 East 3300 South, Suite 100, Salt Lake City, UT 84109, USA and the Quark pulmonary function testing system (K001174) manufactured by COSMED srl, 37 Via dei Piani di Monte Savello Pavona di Albano Laziale (Rome) 00040 Italy.

All three systems are designed for the same intended use and to carry out the same tests. All devices are restricted to be sold by or on the order of a physician. These systems have substantially the same characteristics. The predicate device comparison table is attached.

All systems meet the EMC standard EN60601-1-2 for accuracy of the measurement of flows and volumes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 28 2007

COSMED S.R.L.
C/O Mr. Robert Schiff
President
Schiff & Company
1129 Bloomfield Avenue
West Caldwell, New Jersey 07006

Re: K071533
Trade/Device Name: Fitmate Series COSMED SRL COSMED FITMATE
Regulation Number: 868.1730
Regulation Name: Oxygen Uptake Computer
Regulatory Class: II
Product Code: BZL
Dated: September 6, 2007
Received: September 7, 2007

Dear Mr. Schiff:

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) 276-0120. 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: K071533 Fitmate Series

Device Name: COSMED SRL COSMED FITMATE

Indications For Use:

This device is intended for use in clinical and research application to measure oxygen uptake. Fitmate and Fitmate Pro are designed for the measurement of Resting Metabolic Rate only. Fitmate Pro also measures maximal oxygen uptake (VO2max) that is used for assessing basic pulmonary function.

Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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: K071533