K091412

510(k) Summary

AUG 21 2009

GENERAL INFORMATION

5.1 Type of Submission

Special 510(k) Submission

Submission date: 06/05/2009

5.2 Submitter

Name: Cardinal Health Germany 234 GmbH
(Owned by Cardinal Health Inc.)

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5.3 Establishment Registration Number

9615102

5.4 Common Name or Classification Name

Meter, Peak Flow, Spirometry (CFR 868.1860, Product Code BZH)

5.5 Trade Name

Clean Peak Flow Meter

5.6 Classification

This is a Class II device

5.7 Classification Panel

73 Anesthesiology Part 868
Code BZH

5.8 Reason for Premarket Notification

Device modification to an existing Cardinal Health - device regarding "The New 510(k) Paradigm"

5.9 Legally predicate marketed devices

MicroPeak
K030586 / Code BZH

5.10 Predicate Device Company

Cardinal Health U. K. 232 Limited (Owned by Cardinal Health Inc.)

5.11 Device Description

A peak flow meter is a device used to measure a person's peak expiratory flow rate.

5.12 Intended Use Statement

The Clean Peak Flow Meter simply measures a patient's peak expiratory flow rate in liters/minutes. This is helpful in monitoring respiratory conditions such as asthma.

Targeted population:
Children scale / 50 – 380 liters/minutes
Patients requiring the measurement of peak expiratory flow rate from 6 years on up to 12 years.

Adult scale / 50 – 800 liters/minutes
Patients requiring the measurement of peak expiratory flow rate from 6 years on.

Environment of use:
Places where a patient may require the measurement of their peak expriatory flow rate.

5.13 Required Components

Clean Peak Flow Meter
User Manual

5.14 Summary Table of Comparision

Comparison of the Clean Peak Flow Meter with the MicroPeak with 510(k) # K030586		
	MicroPeak with 510(k) # K030586	**Clean Peak Flow Meter**
Intended Use	The MicroPeak Peak Flow Meter simply measures a patient's peak expiratory flow rate in liters/minutes. This is helpful in monitoring respiratory conditions such as asthma. Targeted population: Patients requiring the measurement of peak expiratory flow rate. Environment of use: Places where a patient may require the measurement of their peak expriatory flow rate.	The Clean Peak Flow Meter simply measures a patient's peak expiratory flow rate in liters/minutes. This is helpful in monitoring respiratory conditions such as asthma. Targeted population: Children scale / 50 – 380 liters/minutes Patients requiring the measurement of peak expiratory flow rate from 6 years on up to 12 years. Adult scale / 50 – 800 liters/minutes Patients requiring the measurement of peak expiratory flow rate from 6 years on.

		Environment of use: Places where a patient may require the measurement of their peak expriatory flow rate.
Design	Single Patient Use	**Identical**
Mouthpiece material	ABS	Polystyrol 454C
Housing material	ABS	**Identical**
Measuring principle	Tension Spring Piston/Pointer	**Identical**
Performance	Range: 60 – 900 L/Min Accuracy: +/- 10% Intra device Precision: +/- 5% Inter device Precision: +/- 5%	Range: 50 – 800 L/Min (adult) 50 – 380 L/Min (children) Accuracy: +/- 10% Intra device Precision: +/- 5% Inter device Precision: +/- 5%
Differences	The only difference is a small difference in the measurement range for adults and a separate range for children. Also the mouthpiece material has changed.	

5.15 Summary of Device Testing

The following practices were followed and monitored for development of the Clean Peak Flow Meter:

The Clean Peak Flow Meter was developed in accordance with the Cardinal Health development standard operating procedures (000490 06 – Design Control).

The risk analysis method used to assess the impact of the Clean Peak Flow Meter was a Failure Modes and Effects Analysis (FMEA).

Safety test procedures demonstrate satisfaction of all safety requirements and mitigation of all identified hazards.

A biological evaluation for Clean Peak Flow Meter mouthpiece was done according ISO 10993 Standard.

5.16 Conclusions

Based on the above, Cardinal Health Germany 234 GmbH concludes that the Clean Peak Flow Meter is substantially equivalent to the legally marketed predicate device and is safe and effective for its intended use, and performs at least as well as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Mr. Thomas Rust
Manager Regulatory Affairs
VIASYS Healthcare GmbH
Leibnizstrasse 7
D-97204 Hoechberg
GERMANY

AUG 21 2009

Re: K091412
Trade/Device Name: Clean Peak Flow Meter
Regulation Number: 21 CFR 868.1860
Regulation Name: Peak-Flow Meter for Spirometry
Regulatory Class: II
Product Code: BZH
Dated: July 20, 2009
Received: July 23, 2009

Dear Mr. Rust:

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Susan Runner

Susan Runner, D.D.S., M.A.
Acting Division 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): K091412

Device Name: Clean Peak Flow Meter

Indications for Use:

The Clean Peak Flow Meter simply measures a patient's peak expiratory flow rate in liters/minutes. This is helpful in monitoring respiratory conditions such as asthma.

Targeted population:

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Environment of use:
Places where a patient may require the measurement of their peak expriatory flow rate.

Prescription Use _____ AND/OR Over-The-Counter Use ___X___
(Part 21 CFR 801 Subpart D) (21 CFR 807 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

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