MAR 2 3 2005

K 042058

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CLEMENT CLARKE INTERNATIONAL

Precision by Tradition

510(k) Summary

Applicant: Clement Clarke Int. Ltd
Edinburgh Way
Harlow
Essex
CM20 2TT
United Kingdom

Establishment Registration No: 9610639

The product is manufactured at the above address

Contact: Mr Philip Hallybone (Quality Manager)

Telephone: +44 (0)1279 414969
Fax +44 (0)1279 635232

Proprietary Name:	OneFlow FVC, OneFlow FVC (kit), OneFlow FVC Screen
Common Name:	Spirometer
Classification Name:	Diagnostic Spirometer
Medical speciality:	Anaesthesiology
Classification:	Class II (performance Standard – National Asthma Education Program's statement on technical standards for Peak Flow meters and the recommendations of the American Thoracic Society, Standardization of Spirometery 1994 Update)
Classification panel	868.1840 [Product code 73 BZG]
Equivalence:	This device is substantially equivalent to the predicate device: Wright Ventilometer VM-1 510(K) ref. K895953

Indications For Use

The OneFlow FVC is a handheld, battery operated, electronic spirometer intended to measure the maximal volume and flow of air that can be moved through a patient's lungs. The device is intended for use with pediatric and adult patients in a variety of clinical settings.

Additional models include the OneFlow FVC (kit), which contains software that can statistically analyze data on a PC; and the OneFlow FVC Screen, which displays the gathered data in comparison with stored predicted values.

Technological Differences with Predicate Device

The technological differences between the OneFlow FVC and the Wright Ventilometer VM-1 are.

- Changes in design to take advantages of advancements in components design and miniaturization namely a more powerful microprocessor and surface mount components on the printed circuit board.
- Changes to plastics used – to use up to date formulations of ABS
- Use of a venturi pressure system in place of backpressure derived from a mechanical resistance device to provide the primary signal from the pressure sensor.
- Lower voltage requirement (VM-1 9V, OneFlow 6V)
- The ability of the OneFlow to store measurements for later analysis (Not FVC Screen)
- The use of illuminated diodes to inform the user of which measurement is being displayed.

Performance Data

Non-clinical performance data has been compiled to support this application by testing the OneFlow FVC in accordance with the methods described in *the American Thoracic Society's document "Standardization of Spirometery" 1994 update*, and comparing the results with the limits for a monitoring device during evaluation.
Simulation of three years typical use has been performed and the difference between the accuracy / repeatability has been evaluated for values obtained before and after the simulation.

Conclusion From Testing & Evaluation

All tests undertaken where found to be within the stated recommendations for a monitoring Spirometer.
Testing to simulate 3 years of use did not alter the accuracy or repeatability of the device.

Signed:..... Date Prepared: 16 November 2004

Mr P Hallybone
Quality Manager

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 3 2005

Mr. Philip Hallybone
Quality Manager
Clement Clarke International Limited
Edinburgh Way,
Harlow, Essex CM20 2TT
United Kingdom

Re: K042058
Trade/Device Name: OneFlow FVC
Regulation Number: 868.1840
Regulation Name: Diagnostic Spirometer
Regulatory Class: II
Product Code: BZG
Dated: March 9, 2005
Received: March 14, 2005

Dear Mr. Hallybone:

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.

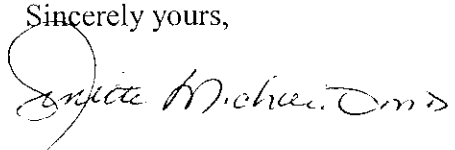
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

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510(k) Number (if known): K042058
Device Name: OneFlow FVC

Indications For Use:

The OneFlow FVC is a handheld, battery operated, electronic Spirometer intended to measure the maximal volume and flow of air that can be moved through a patient's lungs. The device is intended for use with pediatric and adult patients in a variety of clinical settings.

Additional models include the OneFlow FVC (kit), which contains software that can statistically analyze data on a PC; and the OneFlow FVC Screen, which displays the gathered data in comparison with stored predicted values.

Prescription Use _Only
(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 IFNEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

...sion Sign-Off)
...sion of Anesthesiology, General Hospital,
...ection Control, Dental Devices
...(K) Number: K042058