K980960
INTERNATIONAL
Clement Clarke
A HAAG-STREIT COMPANY
Clement Clarke International Ltd., Edinburgh Way, Harlow, Essex CM20 2TT, England
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JUN 10 1998

APPENDIX 1

PRE-MARKET NOTIFICATION CERTIFICATION AND SUMMARY

I certify that I have conducted a reasonable search of all information known or otherwise available to me about the types and causes of safety and/or effectiveness problems that have been reported for the **IN-CHECK**. I further certify that I am aware of the types of problems to which the **IN-CHECK** is susceptible and that the following summary of the types and causes of safety and/or effectiveness problems about the **IN-CHECK** is complete and accurate :

Safety Problems

a) No safety problems should be experienced during use of the device for its intended purpose, and none have been reported for either the **IN-CHECK OR YOULTON INSPIRATORY MINI**. As directed in the Instructions for Use, the users should check that no foreign objects have been introduced into the device.

b) General Medical Standards of cleanliness should be observed in maintaining the instrument, and the mouthpiece should be routinely sterilised in accordance with the User's Instructions.

PRINTED NAME OF PERSON REQUIRED TO SUBMIT 510 (K) :

M.J. WILKINSON

SIGNATURE OF PERSON REQUIRED TO SUBMIT 510 (K) :

.....

TITLE OF PERSON SUBMITTING 510)K) :

QUALITY ASSURANCE MANAGER

NAME OF COMPANY :

CLEMENT CLARKE INTERNATIONAL LIMITED

DATE : 22 December 1997

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 10 1998

Mr. M. J. Wilkinson
Clement Clarke International Ltd.
Edinburgh Way, Harlow
Essex CM20 2TT
United Kingdom

Re: K980960
IN-CHECK Inspiratory Flowmeter
Regulatory Class: II (two)
Product Code: 73 BZH
Dated: March 6, 1998
Received: March 16, 1998

Dear Mr. Wilkinson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

APPENDIX 3

510(K) Number (if known) : Not yet allocated

Device Name : IN-CHECK INSPIRATORY FLOWMETER

Indications for Use :

The **IN-CHECK** is one of a family of simple devices used for monitoring respiratory conditions, and is suitable for use by the Health Care Professional or for home monitoring of nasal or oral inspiratory flow by the patient.

Some uses for the device are :-

1. **Diagnosis of Nasal Obstruction**

   In some patients who complain of nasal obstruction, nasal airway patency is quite normal, and the sympton is due to consciousness of some other abnormality of the nasal cavity such as a prominent turbinate. In some cases, surprisingly low readings are obtained in some patients who are unaware of nasal obstruction, because they have got used to it. Quiet breathing through the nose can in such cases be achieved in spite of a peak nasal inspiratory flow readings as low as 50.

   Such patients are often unaware that they breath through the mouth for much of the time.

   Reversibility of nasal obstruction can be assessed by measuring PNIF after application of a nasal decongestant such as ephedrine by spray or drops. If the PNIF is not raised to a reading of over 100 by such treatment, then the obstruction may be associated with mucosal oedema, extensive polyps or anatomical abnormality. A trial of topical or systemic steroids may also bring the PNIF into the normal range (100 to 300 L/min.).

2. **Assessment of Response to Nasal Provocation**

   Allergen or pharmocological mediator (e.g. histamine) application to the nasal mucosa in doses halving PNIF is usually associated with only minor and transient discomfort. Details of a simplified allergen provocation test using PNIF measurement have been published.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

M. Pugh

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K980960

Prescription Use ✓ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

3. **Home Monitoring of PNIF**

This may be useful in drug or immunotherapy trials in rhinitis, or for assessing the importance of environmental factors at home or work in individual patients with rhinitis. Cyclic changes in nasal airway patency can also be investigated, as can late responses to allergen provocation.

4. **Oral Inspiratory Flow Measurement**

Measurements of sub-maximal inspiratory flows are valuable when training patients in the correct use of medical inhaler devices. Recent studies have indicated target inspiratory flows for many of the inhaled medication devices commonly used to deliver medication in respiratory diseases.

Feedback to the patient from **IN-CHECK** measurement enables the patient to adjust their inhalation technique to best suit their own inhaler.

Note: PNIF = Peak Nasal Inspiratory Flow