



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 29 1999

Mr. E.J. Smith
Harwill Medical (PTY) LTD.
c/o Smith Associates
P.O. Box 4341
Crofton, MD 21114

Re: K992618
RESPALERT
Regulatory Class: II (two)
Product Code: 73 BZH
Dated: July 29, 1999
Received: August 4, 1999

Dear Mr. Smith:

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 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). 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.

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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/dsma/dsmamain.html>".

Sincerely yours,

Christy Foreman for

Ceila M. Witten, Ph.D., M.D.
Acting Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):

Device Name: Whistle Watch *RESPALERT*

Classification Panel: 73BZH, 868.1860

Indications for Use:

The Harwill Medical *RESPALERT* is a peak flow monitor that has been designed to enable adults who suffer from respiratory diseases, such as asthma, chronic bronchitis, emphysema or chronic obstructive lung disease (COPD) to monitor their respiratory status by measuring the rate at which the user can force air out of the lungs. The *RESPALERT* does not create a reading, but the ability to produce a whistle shows that the lung condition is under control.

The *RESPALERT* must be set by a medical doctor or health care worker to a pre-determined measurement using a lung function apparatus at a hospital or clinic. If the patient is unable to produce a whistle when blowing into the *RESPALERT*, it is an indication that medical treatment is necessary or that it is not effective.

Federal (USA) law restricts this device to sale by or on the order of a physician.

Christy Foreman
(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K992618

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use or Over the Counter Use

(Division Sign Off)
Cardiovascular, Respiratory,
and Neurological Devices