DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 31 1998

Mr. Henry Marshall
Medical Industrial Equipment
Falcon Road
Sowton Industrial Estate
Exeter, Devon, EX2 7NA
UNITED KINGDOM

Re: K980489
Vapamasta 6
Regulatory Class: II (two)
Product Code: 73 CAD
Dated: May 26, 1998
Received: June 5, 1998

Dear Mr. Marshall:

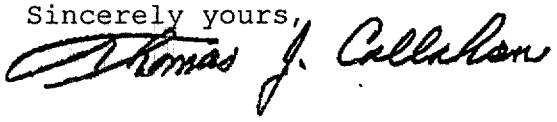
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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.

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,



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

Enclosure

510(k) Number (if known): K980489

Device name: Vapamasta 6 Anaesthetic Vaporiser

Indications For Use:

The Vapamasta 6 Anaesthesia Vaporiser a temperature-compensated concentration-calibrated vaporiser. They are designed to introduce an accurately metered volume of vaporised anaesthetic agent into the fresh gas flow of a continuous-flow anaesthetic apparatus.

Their purpose of these devices is to vaporise an inhalable anaesthetic agent for which they have been calibrated and which is indicated on the labelling. They may be used for the induction and maintenance of a state of anaesthesia in humans during a medical procedure, usually involving a surgical operation. They may additionally be used for veterinary procedures.

The devices are calibrated for a specific anaesthetic agent and vaporisers for the following anaesthetic agents are available in the Vapamasta 6 range; Halothane, Enflurane, Isoflurane or Sevoflurane.

It is recommended by the manufacturer that the device is prepared for use by trained technicians, and that they are used by trained physicians for the purpose for which they are designed and manufactured as described above. It is recommended that suitable agent monitoring should be utilised at all times when these devices are in use. It is recommended that servicing and re-calibration shall be done at intervals prescribed by the manufacturer and performed by fully trained and authorised persons.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Louis Wodos 8-25-98

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K980489

Prescription Use ✓ OR Over The Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)