Section 5
Anaesthetic Vaporizer
Keyed Filler Bottle Adaptor 510(k)

K053564

MAR 3 2006

510(k) Summary
(in accordance with 21 CFR 807.87(h) and 21 CFR 807.92)

1. **Submitter's name and address:**
   Penlon Limited
   Abingdon Science Park
   Barton Lane
   Abingdon
   Oxfordshire, OX14 3PH
   United Kingdom

2. **Submitter's telephone number and fax number:**
   Tel. 011 44 1235 547000
   Fax: 011 44 1235 547041

3. **Contact person:**
   Mr. Alan Green – Technical Director

4. **Date this 510(k) summary prepared:**
   December 20, 2005

5. **Trade/proprietary name of the device:**
   Keyed Filler Bottle Adaptor

6. **Classification name and number of the device:**
   Anesthetic Vaporizer 21CFR 868.5880

7. **Legally marketed predicate device to which substantial equivalence is claimed:**
   Southmedic, Inc. Vapofil Keyed Agent adaptor (Catalogue No. 8907) - FDA 510(k) No. K945993
   Approval to market this device given by FDA on February 22, 1995.
   FDA Device Classification: Class 2
   FDA Regulation Number: 21CFR 868.5880
   FDA Product Code: CAD

8. **Description of the device that is the subject of this premarket notification:**
   The Keyed Filler Bottle Adaptor enables users to connect the bottle, in which the pharmaceutical company supplies specific liquid anaesthetic agents (Halothane, Enflurane, Isoflurane and Sevoflurane), to a compatible filling receptacle provided on an anaesthetic vaporizer, that is attached to an anaesthetic machine. Four versions of the adaptor are available, each one with a colour coded bottle connector and male adaptor (for connecting to the vaporizer). Each adaptor is specific to one of the anaesthetic agents named above and is considered to be an accessory to a vaporizer. This description applies equally to the above named predicate device.

510(k) Summary (continued)
(in accordance with 21 CFR 807.87(h) and 21 CFR 807.92)

9. **Intended use and indication for use:**
The Penlon Keyed Filler Bottle Adaptor is intended to be used to enable the bottle, in which the anaesthetic agent is supplied by the pharmaceutical company, to be connected to the keyed filler port of an anaesthetic vaporizer. The Penlon Keyed Filler Bottle Adaptor provides a flexible connection that allows the liquid agent to be filled into, and drained from, the vaporizer by gravity.

It is indicated for use with bottles of Halothane, Enflurane, Isoflurane and Sevoflurane that provide anaesthesia, via a vaporizer, to a patient connected to an anaesthetic machine.

The Penlon Keyed Filler Bottle Adaptor is an accessory to a restricted Medical device and is intended for use by qualified trained personnel, i.e. Nurses and Technicians under the direction of a Physician. It is supplied as a prescription device, and the labeling indicates this.

The intended use and indications for use apply equally to the above named predicate device.

10. **Technological characteristics:**
The technological characteristics of the Penlon Keyed Filler Bottle Adaptor and the predicate device (the Southmedic. Inc Vapofil Keyed Agent Adaptor are very similar, and any minor differences do not make the Penlon Keyed Filler Bottle Adaptor any less safe and any less effective than the predicate device.

From the above information it is concluded that the Penlon Keyed Filler Adaptor is substantially equivalent to the Southmedic Vapofil Keyed Agent Adaptor.

This concludes the 510(k) Summary.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 3 2006

Penlon Limited
C/O Mr. Barry Pearce
Shortwell & Carr, Incorporated
25 Barker Close
Fishbourne, Chichester, West Sussex
PO18 8BJ
U.K.

Re: K053564
Trade/Device Name: Keyed Filler Bottle Adaptor
Regulation Number: 21 CFR 868.5880
Regulation Name: Anesthetic vaporizer
Regulatory Class: II
Product Code: CAD
Dated: December 20, 2005
Received: December 22, 2005

Dear Mr. Pearce:

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.

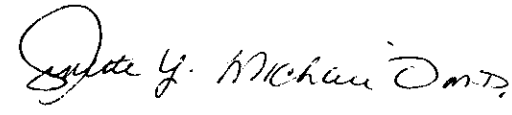
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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) 276-0115. 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

510(k) Number (if known): K053564
K053564

Device Name:
Keyed Filler Bottle Adaptor

Indications For Use:
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Prescription Use Yes (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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[signature]
[illegible] General Hosp
[illegible] Dental Devices
K053564