SEP 2 3 2005

AV-S Anaesthesia Ventilator 510(k) No. K051222 Supplement

Candidate Device
510(k) Summary of Safety and Effectiveness Information

The following information is furnished in accordance with 21 CFR 807.92(a):

1. **Submitter's name and address:**
   Penlon Limited
   Unit A
   Barton Mill
   Audlett Drive
   Abingdon
   Oxfordshire
   OX14 3NJ
   United Kingdom

2. **Submitter's telephone number and fax number:**
   Tel. 001 44 1235 547000
   Fax: 001 44 1235 547041

3. **Contact person:**
   Mr. Anthony Parsons – Quality Manager

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

5. **Trade/proprietary name of the device:**
   AV-S Anaesthesia Ventilator

6. **Classification name and number of the device:**
   Continuous Ventilator 21CFR 868.5895

7. **Legally marketed predicate devices to which substantial equivalence is claimed:**
   1. Penlon Limited AV800 Anaesthesia Ventilator – FDA 510(k) No. K010317 approved by FDA on July 23, 2001.
      FDA Device Classification: Class II
      FDA Classification Number: 21CFR 868.5895
      FDA Classification Code: CBK
   2. Penlon Limited Prima Oxygen Monitor – FDA 510(k) No. K010318 approved by FDA on July 23, 2001
      FDA Device Classification: Class II
      FDA Classification Number: 21CFR 868.1720
      FDA Classification Code: CCL
   3. Datex-Ohmeda Inc. 7900 Anaesthesia Ventilator – FDA 510(k) No. K960964 approved by FDA on September 27, 1996, and K023366 approved by FDA on October 7, 2003
      FDA Device Classification: Class II
      FDA Classification Number: 21CFR 868.5895
      FDA Classification Code: CBK

8. **Description of the device that is the subject of this premarket notification:**
The AV-S Ventilator is a software controlled multi-mode ventilator designed for mechanical ventilation of adult and paediatric patients under general anaesthesia. In addition, in spontaneous mode, it can be used to monitor spontaneously breathing patients. It is designed for use in closed circuit anaesthesia and also to drive a Mapleson D circuit.

510(k) Supplement additional information:
The AV-S Ventilator is also available with a remote display screen unit that can be affixed to an anaesthesia machine and be located remotely from the ventilator control unit. The display screen is affixed to the anaesthesia machine by means of a swivel mounting arm. An interconnecting cable is provided to transmit data between the control unit and the remote display screen unit.

9. **Intended use and indication for use:**
The AV-S Anaesthesia Ventilator is intended to provide continuous mechanical ventilatory support during general anaesthesia. The ventilator is a restricted medical device intended for use by qualified trained personnel, i.e. Nurses and Technicians under the direction of a Physician. Specifically the ventilator is applicable for adult and pediatric patients.

The AV-S Anaesthesia ventilator is a prescription device and the labeling indicates this.

10. **Technological characteristics:**
The technological characteristics of the AV-S and the predicate devices, the Penlon AV 800 and the Datex-Ohmeda 7900 (also known as SmartVent), are very similar in that they are all software controlled anaesthesia ventilators. The indications for use of all three devices are the same.

The main technological difference is that the AV-S incorporates the technology of the Penlon Prima Oxygen monitor, an approved device that was formally marketed separately, and some additional software that provides for three advanced spontaneous breathing support modes.

This concludes the 510(k) summary.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 3 2005

Penlon Limited
C/O Mr. Barry Pearce
Shotwell & Carr, Incorporated
25 Barker, Close
Fishbourne, Chichester
West Sussex,
UNITED KINGDOM P018 8BJ

Re: K051222
Trade/Device Name: AV-S ANAESTHESIA VENTILATOR
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous ventilator
Regulatory Class: II
Product Code: CBK
Dated: September 1, 2005
Received: September 19, 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) 276-0120. 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 Device
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

K051222

Device Name:

AV-S Anaesthesia Ventilator

Indications For Use:

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The AV-S Anaesthesia ventilator is a prescription device and the labelling indicates this.

Prescription Use _____ YES AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (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)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K051222