K060331

Section 5
Sigma Alpha Vaporizer 510(k)

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

MAY 10 [illegible]

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:**
February 3, 2006

5. **Trade/proprietary name of the device:**
Sigma Alpha Vaporizer

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

7. **Legally marketed predicate devices to which substantial equivalence is claimed:**
   1. Penlon Limited Sigma Delta Vaporizer – FDA 510(k) No. K002343
      Approval to market this device given by FDA on June 8, 2001.
      FDA Device Classification: Class 2
      FDA Regulation Number: 21CFR 868.5880
      FDA Product Code: CAD

   2. Datex-Ohmeda Inc. Tec 6 Plus and Tec 6 Plus NAD Variant Anaesthesia Vaporizer – FDA 510(k) No. K000275
      Approval to market this device given by FDA on April 12, 2000.
      FDA Device Classification: Class 2
      FDA Regulation Number: 21CFR 868.5880
      FDA Product Code: CAD

   3. Drägar Medical D-Vapor Anaesthesia Vaporizer – FDA 510(k) No. K042276
      Approval to market this device given by FDA on September 23, 2004.
      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 Sigma Alpha Vaporizer is an electronic calibrated vaporizer that is

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

designed to enrich the fresh gas flow of a continuous flow anaesthesia machine, when the vaporizer is connected directly between the flowmeter and the common gas outlet of the machine. The device has been developed in close co-operation with clinicians and the anaesthetic agent manufacturer.

This description applies equally to the above named predicate devices.

9. Intended use and indication for use:

The Sigma Alpha Vaporizer vaporizes a specific anaesthetic agent - Suprane®, also know as Desflurane - and delivers controlled concentrations of the vaporized anaesthetic agent into a fresh gas that is then breathed by the patient.

The Sigma Alpha vaporizer is indicated for use by both adult and pediatric patients.

The Sigma Alpha vaporizer is not intended to be used with Enflurane, Halothane, Isoflurane or Sevoflurane, or for use in a breathing circuit.

The Sigma Alpha vaporizer is a restricted medical device 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 devices.

10. Technological characteristics:

The technological characteristics of the Sigma Alpha and the predicate Devices (the Penlon Sigma, Datex-Ohmeda Inc. Tec 6 Plus, Datex-Ohmeda Inc Tec 6 Plus NAD Variant, and Drägar Medical D-Vapor Anaesthesia Vaporizer are very similar, and any minor differences do not make the Sigma Alpha any less safe and effective than the predicate devices.

From the above information it is concluded that the Penlon Sigma Alpha Vaporizer is substantially equivalent to the above named predicate devices.

This concludes the 510(k) Summary.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 10 2006

Penlon Limited
C/O Mr. Barry Pearce
Vice President
Shotwell & Carr, Incorporated
25 Barker Close
Fishbourne, Chichester
West Sussex, P0188BJ
United Kingdom

Re: K060331
Trade/Device Name: Sigma Alpha Vaporizer
Regulation Number: 868.5880
Regulation Name: Anesthetic Vaporizer
Regulatory Class: II
Product Code: CAD
Dated: February 3, 2006
Received: February 9, 2006

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.

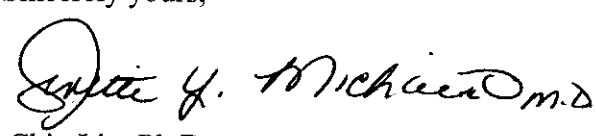
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

Section 4
Sigma Alpha Vaporizer 510(k)

Indications For Use

510(k) number (if known): **Page 1 of 1**

Unknown - not yet assigned by FDA.

Device name:

Sigma Alpha Vaporizer

Indications for use:

The Sigma Alpha Vaporizer vaporizes a specific anaesthetic agent - Suprane®, also know as Desflurane - and delivers controlled concentrations of the vaporized anaesthetic agent into a fresh gas that is then breathed by the patient.

The Sigma Alpha Vaporizer is indicated for use by both adult and pediatric patients.

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The Sigma Alpha Vaporizer is a restricted medical device 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.

Prescription Use __Yes__ AND/OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 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)
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(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K060331