K981754

JUN 16 1998

510(k) Summary of Safety and Effectiveness
In accordance with SMDA '90

Porter Instrument Co., Inc
245 Township Line Road
PO Box 907
Hatfield PA 19440-0907

May 15, 1998

Contact: Stephen D. Loeffler, Manager of Engineering and Quality
Telephone: 215-723-4000

Common/Usual Product Name: Automatic Vacuum Switch, dental

Trade/Proprietary Name: Porter Instrument Company, Inc.,
Automatic Vacuum Switch (AVS)

Classification Name:

Anesthesiology
Non-classified*
Accessory to § 868.5430
Gas scavenging apparatus. Class 2

Substantial Equivalence[1] to:

510(k) #	Name	Applicant
K761140	Double Mask	Fraser Sweatman
K802067	Clean Air Pollution Reduction System	Porter Instrument Co., Inc.

Device Description:

In accordance with section 510(k) for the Federal Food, Drug, and Cosmetic Act, Porter Instrument Company, Inc. intends to introduce into interstate commerce the Automatic Vacuum Switch (AVS) device. The automatic interlock switch (AVS) is a device intended to assure that analgesic gases cannot be turned on unless an activated scavenging system is present.

[1] The term "substantially equivalent" as use herein is intended to be a determination of substantial equivalence from an FDA –regulatory point of view under the Federal Food, Drug, and Cosmetic Act and relates to the fact that the product can be marketed without premarket approval or reclassification. These products may be considered distinct from a patient point of view. The term "substantially equivalent" is not applicable to and does not diminish any patient claims related to this product or the technology used to manufacture the product.

Intended Use

For control of vacuum flow in a gas scavenging apparatus, used as an accessory in Porter Instrument Company's Nitrous Oxide Sedation Systems with Dental Analgesia Gas Machines (flowmeters).

Substantial Equivalence

The Automatic Vacuum Switch (AVS) is substantially equivalent, in **comparison** to the legally marketed device, because it:

- has the same intended use as the predicate device; and
- has different technological characteristics, and
- the information submitted to FDA;
- does not raise new questions of safety and effectiveness, and
- demonstrates that the Automatic Vacuum Switch (AVS) is as safe and as effective as the legally marketed device

Different technological characteristics include, but are not limited to, changes in materials, design, energy sources, and principles of operation.

Porter Instrument Company's claim of substantial equivalence does not mean the compared devices are identical but that the substantial equivalence is established with respect to: intended use, design, energy used or delivered, materials, performance, safety, effectiveness, labeling, biocompatibility, standards, and other applicable characteristics.

Safety and Effectiveness

All finished products are function tested and must meet all required specifications before release to distribution. A range of tests is required for release, which include, but are not limited to; a functional test and a visual inspection (both in process and finished product).

The function test and the visual inspection are defined in both Porter's manufacturing procedure and inspection procedure. These documents are established test procedures, which conform to the product design specifications.

All procedures and records for this product are approved, released, distributed and revised according to Porter Instrument Company's Document & Data Control procedure QSP 5-1.

Qualification of the Automatic Vacuum Switch (AVS) included a detailed risk assessment, which attended to a Failure Mode Effects Analysis and a Hazard Analysis. Additional testing covered: backpressure, delivery and vacuum flow, internal and external leak testing, complete system testing and simulated use testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 16 1998

Mr. Stephen D. Loeffler
Porter Instrument Company, Inc.
245 Township Line Road
P.O. Box 907
Hatfield, PA 19440-0907

Re: K981754
Trade Name: Automatic Vacuum Switch (AVS)
Regulatory Class: Unclassified
Product Code: 73 CBN
Dated: May 15, 1998
Received: May 18, 1998

Dear Mr. Loeffler:

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 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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/dsmamain.html".

Sincerely yours,

Thomas J. Callahan

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

Enclosure

Statement of Indications for Use

The intended use of the AVS accessory is to control the vacuum flow in a gas scavenging apparatus.

Special 510(k) statement: The intended use of the modified device, as described in our labeling, has not changed as a result of the modifications.

Wally Epperson MD

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K981754