DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

MAY 11 2017

Mr. Paul Silva
Regulatory Affairs Coordinator
Pentax Precision Instrument Corporation
3117 Commerce Parkway
Miramar, Florida 33025

Re: K964815
Trade/Device Name: AP-4000, Air Pulse Sensory Stimulator
Regulation Number: 21 CFR 882.1200
Regulation Name: Two-point discriminator
Regulatory Class: Class I
Product Code: LLN
Dated: August 12, 1997
Received: August 13, 1997

Dear Mr. Silva:

This letter corrects our substantially equivalent letter of September 4, 1997.

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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 Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael J. Hoffmann -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if Known): K964815

Device Name: AP-4000, Air Pulse Sensory Stimulator

Indications for Use:

The AP-4000, Air Pulse Sensory Stimulator, is intended to elicit Laryngeal Closure Reflex (Swallow) and to measure the sensory discrimination threshold at which the reflex occurs in the area of the Upper Airway innervated by the Superior Laryngeal Nerve. The structures being stimulated in the area of the Upper Airway innervated by the Superior Laryngeal Nerve are: the Left and Right Anterior Wall of the Pyriform Sinus and the Left and Right Aryepiglottic Folds. The device is intended to be used with the Pentax FNL-10AP or FNL-10RAP, Fiber Naso -Pharyngo- Laryngo Scope, introduced per nasally in Adult and Pediatric patient populations with suspected Dysphagia.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Thomas J. Callahan

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K964815

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

(Optional Format 1-2-96)

K964815

DOCUMENT NUMBER: KS053 **PAGE 1 OF 1**
DATE PREPARED: 03-19-97 **PREPARED BY:** PAUL SILVA

510(K) SUMMARY: AP-4000, AIR PULSE SENSORY STIMULATOR

SUBMITTER INFORMATION: Paul Silva
Pentax Precision Instrument Corporation
30 Ramland Road
Orangeburg, NY, 10962
TEL: (914)-365-0700

SEP - 4 1997

NAME OF DEVICE: Trade Name: AP-4000, Air Pulse Sensory Stimulator
Classification Name: Endoscope and Accessories (78KOG) {876.1500}

PREDICATED DEVICE(S) INFORMATION:

FNL-15P2, Fiber NasoPharyngo(Laryngo)scope	Pentax	K921707
Reflex Hammer, Manual	*Class 1 device, no 510(k) clearance	
Keeler Non Contact Tonometer	Keeler Instruments	K870750
Companion 335, Nasal CPAP System	Nellcor Puritan Bennett	K942210
Motility Catheter	MAI	K823701
Infusion Pump	MAI	K823700
Synetics liberty System, PC Polygraph	Synetics	K904625

DEVICE DESCRIPTION:

The AP-4000, Air Pulse Sensory Stimulator, is an endoscopic accessory that must be used with the Pentax FNL-10AP or FNL-10RAP, Fiber Naso-Pharyngo-(Laryngo) Scopes. The AP-4000 is a software controlled device. The device contains an Air Pump and the mechanics to control the pressure of a 50 millisecond (ms) air pulse, delivered through the FNL-10AP working channel. The device is connected to the endoscope working channel with an Air Supply Tube (two pieces are included with the device as standard set components). The device front panel has controls and displays to allow a desired pressure for the 50 ms air pulse to be selected (in the range 2 mm Hg to 10 mm Hg), the air pulse to be initiated, and the actual pressure of the delivered air pulse to be displayed. There are connections for the Air Supply Tube (to the endoscope working channel), a pneumatic footswitch (alternate control to initiate air pulse, one piece is included as a standard set component), and an RS-232 connection so that unit displays may be available to other system peripheral devices (Addon Camera).

INTENDED USE:

The AP-4000, Air Pulse Sensory Stimulator, is intended to elicit Laryngeal Closure Reflex (Swallow) and to measure the sensory discrimination threshold at which the reflex occurs in the area of the Upper Airway innervated by the Superior Laryngeal Nerve. The structures being stimulated in the area of the Upper Airway innervated by the Superior Laryngeal Nerve are: the Left and Right Anterior Wall of the Pyriform Sinus and the Left and Right Aryepiglottic Folds. The device is intended to be used with the Pentax FNL-10AP or FNL-10RAP, Fiber Naso -Pharyngo- Laryngo Scope, introduced per nasally in Adult and Pediatric patient populations with suspected Dysphagia.

COMPARISON TO PREDICATED DEVICE(S):

The submission for substantial equivalence included AP-4000, Air Pulse Sensory Stimulator, specifications, literature, the identification of standard set components and optional accessories. Comparison tables were provided to illustrate the comparisons to the predicated devices. The submission for substantial equivalence was not based on an assessment of clinical performance data.