

K964815

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

SUBMITTER INFORMATION: Paul Silva
Pentax Precision Instrument Corporation
30 Ramland Road
Orangeburg, NY, 10962 SEP - 4 1997
TEL: (914)-365-0700

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.



SEP - 4 1997

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K964815
Trade Name: AP-4000, Air Pulse Sensory Stimulator
Regulatory Class: Unclassified
Product Code: 84LLN
Dated: August 12, 1997
Received: August 13, 1997

Dear Mr. Silva:

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 (Pre-market 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 pre-market 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 at (301) 443-6597.

Sincerely yours,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological 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 Piriform 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
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____