K081778

Instrumentation Industries, Inc.
We make Respiratory Care Work!

SEP 12 2008

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Date Prepared: June 20, 2008
Revised: August 11, 2008
Contact Person: Edward C. Horey
Submitter: Doris F. Walter
Official Correspondent for Instrumentation Industries, Inc.: Edward C. Horey

510(k) SUMMARY
For
NS Airway Pressure Monitors

Trade Name	NS Series Vacuum/Pressure Gauges
Common Name	Pressure Monitor
Classification Name	Airway Pressure Monitor
Regulation	21 CFR 868.2600
Predicate Device	Instrumentation Industries, Inc. - BE 148 – Preamendment device Anesthesia Associates, Inc. Model # 00-199 – Preamendment device
Device Description	The NS Airway Pressure Gauges are intended to measure airway pressures of up to 30, 60 or 120 cm. H20, dependent upon the specific model used.
Intended Use of the Device NS 30-PBS NS 60-PBS NS 60-TRS NS 30-TRS NS 60-TBS NS 120-TRS	The Instrumentation Industries, Inc. NS Series Airway Pressure Monitors are devices used to monitor patient airway pressure during ventilation within a breathing circuit. The pressure gauge is placed in the patient circuit at a point that provides optimal airway pressure readings. These devices are intended to be used by or on the order of a physician.
NS 60-TBS-CP NS 60-TRS-CP	During ventilation, the NS Series Cuff Pressure Monitors are devices used to periodically monitor endotracheal or tracheostomy tube balloon pressure to assure an adequate seal between the tube and the tracheal wall. These devices are intended to be used by or on the order of a physician.

Technological Characteristics	**Similarities:** 1. The function of the BE 148, the NS Series Pressure Gauges, and Anesthesia Associates, Inc. Model # 00-199, are the same. All are analog-faced manometers used to measure low pressures within a patient breathing circuit. 2. The performance of the BE 148, the NS Series Vacuum/Pressure Gauges and Anesthesia Associates, Inc. Model # 00-199 are similar. 3. The anticipated usage of all of the devices is the same. All three types of airway pressure monitors can be used to measure positive pressure as well as negative. 4. The anticipated function and usage of the NS 60-TBS-CP, the NS 60-TRS-CP and the Smith Portex Cuff Pressure Indicator are the same. **Differences:** The capacity varies among them: - The BE 148 range = -60-0-60 cm H_2O. - The NS Series are offered in three pressure ranges: -30-0-30, -60-0-60, -120-0-120 cm H_2O. - The Anesthesia Associates, Inc. Model # 00-199 range = -40-0-80 cm H_2O - The Smith Portex Cuff Pressure Indicator measures only positive pressure with a range of 0-60 cm H_2O, while the NS Series CP monitors have a range of -60-0-60 cm H_2O.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 12 2008

Ms. Doris F. Walter
Regulatory Affairs/Quality Assurance Manager
Instrumentation Industries, Incorporated
2990 Industrial Boulevard
Bethel Park, Pennsylvania 15102-2536

Re: K081778
Trade/Device Name: NS Series Airway Pressure Monitors
NS Series Cuff Pressure Monitors
Regulation Number: 21 CFR 868.2600
Regulation Name: Airway Pressure Monitor
Regulatory Class: II
Product Code: CAP
Dated: August 11, 2008
Received: August 13, 2008

Dear Ms. Walter:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 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

Indications for Use

510(k) Number (if known):

This is an initial submission; no number has yet been assigned.

Statement of Indications for Use:

The Instrumentation Industries, Inc. NS Series Airway Pressure Monitors are devices used to monitor patient airway pressure during ventilation within a breathing circuit. The pressure gauge is placed in the patient circuit at a point that provides optimal airway pressure readings.

These devices are intended to be used by or on the order of a physician.

Prescription Use ___√___ 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)

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

510(k) Number: K061778

Statement of Indications for Use:

B. During ventilation, the NS Series Cuff Pressure Monitors are devices used to periodically monitor endotracheal or tracheostomy tube balloon pressure to assure an adequate seal between the tube and the tracheal wall.

These devices are intended to be used by or on the order of a physician.

Prescription Use ___√___ (Part 21 CFR 801 Subpart D) And/Or Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

(Division Sign-Off)
Division of Anesthesiology, General Hospital
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