May 1, 2019

Instrumentation Industries, Inc.
Doris Walter
RA/QA Manager
2990 Industrial Blvd.
Bethel Park, Pennsylvania 15102

Re: K180510
Trade/Device Name: NS 120P-TRS Airway Pressure Gauge
Regulation Number: 21 CFR 868.2600
Regulation Name: Monitor, Airway Pressure
Regulatory Class: Class II
Product Code: CAP
Dated: April 1, 2019
Received: April 1, 2019

Dear Doris 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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 Part

801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180510

Device Name
NS 120P-TRS Pressure Gauge

Indications for Use *(Describe)*

The Instrumentation Industries, Inc. NS 120P-TRS Airway Pressure Monitor is a device used to monitor patient airway pressure during ventilation with a manual resuscitation device or bag/mask unit.

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

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Date Prepared: 9/5/2018;
Contact Person/Submitter: Doris F. Walter
Official Correspondent for Instrumentation Industries, Inc.: Edward C. Horey

510(k) SUMMARY
NS 120P-TRS Pressure Gauge
K180510

Trade Name of Subject Device	NS 120P-TRS Pressure Gauge
Common Name	Monitor, Airway Pressure
Classification	Class II
Regulation	21 CFR 868.2600
Product Code	CAP
Predicate Device	NS 120-TRS Vacuum/Pressure Gauge K081778 Distributed by Instrumentation Industries, Inc.
Device Description	The Instrumentation Industries, Inc. NS 120P-TRS airway pressure monitor measures positive pressures from 0-120cm H_2O during manual ventilation. The device contains a diaphragm capsule which inflates when positive pressure is introduced and collapses when the pressure decreases. Through several internal, interconnected, movements caused by the inflating/deflating diaphragm, the pointer on the face of the gauge moves to indicate accurate pressure.
Indications for Use	The Instrumentation Industries, Inc. NS 120P-TRS Airway Pressure Monitor is a device used to monitor patient airway pressure during ventilation with a manual resuscitation device or bag/mask unit. These devices are intended to be used by or on the order of a physician.

Intended Use of the Device	The NS 120P-TRS would be used in-line with a Resuscitation Bag Mask Unit to monitor positive pressures when manually ventilating a patient, to assure that safe prescribed pressures are not exceeded.
Where Used	Hospital, Physician Office, Emergency services.

Material and Physical Characteristics

NS 120P-TRS Subject Device	**NS 120-TRS Predicate Device**
Pressure Range: 0 – 120cm H_2O	-120cm H_2O – 0 – +120cm H_2O
Accuracy: +/- 1.6% full scale (1.92 cm H_2O)	Accuracy: +/- 1.6% full scale (3.8 cm H_2O)
Measuring element: Copper alloy diaphragm capsule	Same
Connection: ¼" NPT, brass	Same
Case: Black ABS	Same
Assembly Screws: Steel	Same
Lens: Acrylic	Same
Pointer: Black finished aluminum	Same
Dial: Aluminum, white background with black scale.	Same
UV-resistant Movement: Brass and nickel-silver with highly-polished bearing surfaces.	Same

Biocompatibility: No new biocompatibility testing has been performed. Biocompatibility information is leveraged from the predicate device. All of the materials and processing of the final finished form of the subject device are identical to those of the predicate device. In accordance with the FDA 2016 Biocompatibility Guidance Document, Attachment F, the general example statement for Comparison to the previously marketed device is utilized as follows:

The materials used in the NS 120P-TRS, manufactured by NoShok, are identical to the materials used in the NS 120-TRS, also manufactured by NoShok, as approved in K081778 in formulation, processing, and sterilization, and no other chemicals have been added.

Technological Characteristics	Both the subject and predicate device contain the exact same components but the technological characteristics of the subject and predicate devices are different due to an adjustable tab. One technological modification, the physical adjustment of the abovementioned tab, dictates whether the gauge will read both negative and positive pressure, or whether it will read only positive pressure. The technological modification: Adjusting the tab at different heights controls the movement of an internal lever: - For the predicate device, the tab is bent higher, allowing greater movement of the upper lever so that both positive and negative pressure can be introduced for the full range of -120cm H_2O to +120cm H_2O. - For the Subject device, the tab is bent lower to permit the upper lever to move in the positive direction only, within the range of 0cm H_2O to +120cm H_2O.

Performance Testing: Summary of non-clinical testing data

The objectives of the validation testing were to:

1. Ensure that the new NS 120P-TRS pressure gauges (subject device) met the accuracy tolerance of 1.6% of full scale (±1.9cm H_20)
2. Compare the accuracy testing results of the new NS 120P-TRS pressure gauge against a similar, currently-marketed vacuum/pressure gauge already in our product line, the NS 120-TRS vacuum/pressure gauge (predicate device). Accuracy tolerance of the predicate device is also 1.6% of full scale (±3.8cm H_20). Please note that the tolerance is doubled for the predicate device because its scale is twice the range of the NS 120P-TRS (subject) device as the predicate device measures both positive and negative pressure.
3) Compare needle responsiveness of subject and predicate device. The acceptance criteria for responsiveness of the needle movement is that both gauges must respond instantly to pressurization changes.

The following tables summarize the comparative results of non-clinical testing performed for the subject NS 120P-TRS and NS 120-TRS predicate devices.

Accuracy Test Comparison for NS 120P-TRS and NS 120-TRS

Device	Number of Samples	Vendor's Accuracy Specification	Average Accuracy Difference at 60 cm H_20 Pressure	Average Accuracy Difference at 120 cm H_20 Pressure	Pass or Fail
NS 120P-TRS (Subject)	50	±1.9cm H_20	0.6 cm H_20	0.9 cm H_20	Pass
NS 120-TRS (Predicate)	10	±3.8cm H_20	0.8 cm H_20	1.8 cm H_20	Pass

Responsiveness Test Comparison for NS 120P-TRS and NS 120-TRS

Device	Number of Samples	Instrumentation Industries Inc.'s Response Specification	Pass/Fail	Notes
NS 120P-TRS (Subject)	50	Must respond instantly to pressure	Pass	
NS 120-TRS (Predicate)	10	Must respond instantly to pressure and vacuum	Pass	The vacuum readings for the predicate gauge are not really relevant for this comparison as the subject gauge has no vacuum capability, but are included for completeness.

Summary of testing:

Validation testing shows that the NS 120P-TRS pressure gauge meets the manufacturer's and Instrumentation Industries Inc.'s accuracy specification and has needle movement that is responsive to pressure changes, and thus meets all of the pre-defined acceptance criteria, substantially equivalent to the predicate NS 120-TRS device.

Based upon these testing results, the subject device, NS 120P-TRS Pressure Gauge has been found to be substantially equivalent when measuring pressure to the predicate NS 120-TRS Vacuum/Pressure gauge.

Conclusion:	The NS 120P-TRS has been compared against a currently marketed device for the determination of substantial equivalency when used for monitoring positive pressure. The NS 120P-TRS has been found to be substantially equivalent to the NS 120-TRS.