October 18, 2018

TNI Medical AG
℅ Dave Yungvirt
Official Correspondent
Third Party Review Group, LLC
The Old Station House
24 Lackawanna Place
Millburn, New Jersey 07041

Re: K180474
Trade/Device Name: TNI softFlow 50
Regulation Number: 21 CFR 868.5450
Regulation Name: Respiratory gas humidifier
Regulatory Class: Class II
Product Code: BTT
Dated: September 21, 2018
Received: September 24, 2018

Dear Dave Yungvirt:

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,

for 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K180474

Device Name
TNI softFlow 50

Indications for Use *(Describe)*
The TNI softFlow 50 is for the treatment of spontaneously breathing patients who would benefit from receiving high flow warmed and humidified respiratory gases. The TNI softFlow 50 is for adult patients in hospitals and long-term care facilities. The flow may be from 10-50 L/min.

The TNI softFlow 50 is not indicated for life support measures.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY – K180474

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR §807.92:

I. SUBMITTER

TNI medical AG
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Contact Person: Peter Urban
Date Prepared: October 18, 2018

II. DEVICE

Name of Device:	TNI softFlow 50
Classification Name:	Humidifier, Respiratory Gas, (Direct Patient Interface)
Regulation:	21 CFR §868.5450
Regulatory Class:	Class II
Product Classification Code:	BTT

III. PREDICATE DEVICE

Predicate Manufacturer:	FISHER & PAYKEL HEALTHCARE, LTD.
Predicate Trade Name:	AIRVO 2 HUMIDIFIER
Predicate 510(k):	K131895

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The softFlow 50 system is a high flow heated humidifier for respiratory gases with integrated flow source and a heated breathing tube to deliver conditioned respiratory gases to a patient. The air or air/oxygen mixture is both humidified and heated. A nasal cannula serves as applicator, similar to the nasal cannula used during oxygen ventilation therapy. The nasal applicator is no compatible with a tracheostoma. The nasal applicator is sold separately as a disposable accessory that is replaced after 14 days (336 hours).

The softFlow 50 is for the treatment of spontaneously breathing adult patients in hospitals and long-term care facilities who would benefit from receiving high flow warmed and humidified respiratory gases. The flow may be from 10-50 L/min depending on the patient interface.

The humidifier clinic complete is sold separately so that the patient can replace the airlift, the humidification chamber, and the bacterial filter. The humidifier clinic is sold separately as a disposable accessory that is replaced weekly.

V. INDICATIONS FOR USE

The TNI softFlow 50 is for the treatment of spontaneously breathing patients who would benefit from receiving high flow warmed and humidified respiratory gases. The TNI softFlow 50 is for adult patients in hospitals and long-term care facilities. The flow may be from 10-50 L/min.
The TNI softFlow 50 is not indicated for life support measures.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVCE

The following characteristics were compared between the subject device and the predicate device in order to demonstrate substantial equivalence:

- Indications for Use – The predicate and subject device have nearly identical intended use and indications for use with the exception that the TNI softFlow 50 does not include patients with the upper airways bypassed. There are three minor differences between the predicate indications and the indications for use for the subject device:
  1. the overall range of flow rate range of the predicate device is slightly larger (2-60 L/min vs. 10-50 L/min)
  2. the indications for use of the subject device exclude life support measures; and
  3. the exclusion of patients with upper airways bypassed.
- Materials – The predicate and subject device both are made from molded plastics and use a metal heater plate for the humidification chamber.
- Design – The predicate and subject device include an integrated blower and humidifier with chamber and heated breathing tube. Both devices also allow for mixing with supplemental oxygen.
- Energy Source – The predicate and subject device are powered electrically from mains supply to power the blower and heating.
- Other Design Features – The predicate and subject device are also substantially equivalent with regard to the following design features:
  - Temperature range
  - Operating principles
  - Alarms
  - User interface
  - Display
  - Software and hardware controls
- Performance Testing – The predicate and subject device both were evaluated using benchtop testing for flow rates and humidity to ensure that the user needs were met.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination:

- EN 62353:2014 Recurrent Test and Repair Test
- Air and Oxygen Flow Rate Test
- Mixing Chamber Test
- Humidifier Measurement Test
- FiO2 Measurement Test

Sterilization & Shelf-life

The shelf-life of the softFlow 50 is 4 years 10 months (based upon the shelf-life of the capacitor), while 6-months is claimed for the shelf-life of the nasal applicator. The shelf-life for the humidifier clinic is based upon the expiration of the bacterial filter.

Biocompatibility Testing

The following testing was performed in order to demonstrate biocompatibility:

- Emissions of VOCs
- Genotoxicity
- Intracutaneous Irritation
- Cytotoxicity
- Acute Systemic Toxicity
- Sensitization (Guinea Pig Max)
- Chemical Characterization
- Particulate Matter

Software Verification and Validation Testing

Software verification and validation testing were performed in accordance with IEC 62304:2006 to ensure operation of embedded product software, and a software/hardware usability risk analysis was performed.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety testing and EMC testing were conducted in accordance with IEC 60601-1:2005, MOD and IEC 60601-1-2:2014 to ensure electrical safety and electromagnetic compatibility. A study was also completed in order to demonstrate that the applied parts and accessories are not negatively affected by cleaning and disinfection.

Mechanical and acoustic Testing

No mechanical or acoustic testing was performed to demonstrate safety or effectiveness beyond the performance testing listed at the beginning of this section. This testing includes alarms testing in accordance with IEC 60601-1-8:2006. Compliance to respiratory humidification systems was also by testing in accordance with ISO 8185:2007.

Animal Study & Clinical Studies

Animal performance testing and clinical testing was not required to demonstrate safety and effectiveness of the TNI softFlow 50. Instead, substantial equivalence is based upon benchtop performance testing.

VIII. CONCLUSIONS

Testing carried out on the TNI softFlow 50 indicates that the system meets the performance functional requirements. The device complies with the standards for medical electrical equipment, biocompatibility and performance. The results obtained for the TNI softFlow 50 are substantially equivalent to the predicate AIRVO2. It can be concluded that the TNI softFlow 50 is substantially equivalent to the AIRVO2 predicate device.