June 14, 2024

Invent Medical Corporation
David Gramse
Sr. Director, Regulatory Affairs
2788 Loker Ave. W.
Carlsbad, California 92010

Re: K233707
Trade/Device Name: Hft150
Regulation Number: 21 CFR 868.5450
Regulation Name: Respiratory gas humidifier
Regulatory Class: Class II
Product Code: BTT
Dated: May 9, 2024
Received: May 9, 2024

Dear David Gramse:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ethan L. Nyberg -S

Ethan Nyberg, Ph.D.
Assistant Director
DHT1C: Division of Sleep Disordered
Breathing, Respiratory and

Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K233707

Device Name

HFT150

Indications for Use *(Describe)*

HFT150 is for spontaneously breathing adult and pediatric patients (10 kg and up) who would benefit from receiving high flow warmed and humidified respiratory gases. The flow may be from 2 - 60 L/min depending on the patient interface. HFT150 is used in hospital and professional healthcare environments.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

HFT150 510(k) Summary

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

SUBMITTER:	Invent Medical Corporation 2788 Loker Ave. W. Carlsbad, CA 92010
Contact Person:	David Gramse Sr. Director Regulatory Affairs P: (442) 888-7673 E: dave@invent-medical.com

Preparation Date:	May 08, 2024
Name of Device:	HFT150
Common or Usual Name:	Humidifier, Respiratory Gas, (Direct Patient Interface)
Regulation Name:	Respiratory gas humidifier
Regulation Number:	21 CFR 868.5450
Product Code:	BTT
Device Class:	Class 2

Primary Predicate:

Trade Name:	AIRVO 2 Series Humidifier
510(k) Number:	K131895

Reference Device:

Trade Name:	ApneaLink Air
510(k) Number:	K143272

Reference Device:

Trade Name:	HVT 2.0
510(k) Number:	K203357

DEVICE DESCRIPTION:

The HFT150 is a heated humidifier with integrated flow source and a heated breathing tube to deliver warmed and humidified gas flow to a patient. The HFT150 includes an integrated oxygen module, delivering an oxygen range of 21% to 100% to the patients.

The HFT150 humidifier is comprised of two connected functional units. One is a motorized blower assembly that provides air flow and the delivery of supplemental oxygen to patients via an integrated oxygen module. The blower speed is directly related to total delivered flow and is controlled by software with a flow sensor. The blower assembly output connects directly to an integrated humidification tub.

The second functional unit of the HFT150 is a heated humidifier. The tub is integral to the HFT150. Software monitors ambient temperature, humidity, and flow to optimize the humidity delivery to the patient and minimize condensation in the patient circuit. The HFT150 is protected from contaminants and pathogens by an integral anti-bacterial filter. The nasal cannulas, heated tubes, and water tubs are disposable and are for single use only. The HFT150 may be operated by nurses, respiratory therapists, or doctors and water tubs are disposable and are for single use only. The HFT150 may be operated by nurses, respiratory therapists, or doctors.

Indications for Use

HFT150 is for spontaneously breathing adult and pediatric patients (10 kg and up) who would benefit from receiving high flow warmed and humidified respiratory gases. The flow may be from 2 - 60 L/min depending on the patient interface. HFT150 is used in hospital and professional healthcare environments.

SUBJECT AND PREDICATE DEVICE INDICATIONS FOR USE COMPARISON:

HFT150 Indications for Use (Subject Device – K233707)	AIRVO 2 Series Humidifier (Primary Predicate Device – K131895)	Assessment of Differences
HFT150 is for spontaneously breathing adult and pediatric patients (10 kg and up) who would benefit from receiving high flow warmed and humidified respiratory gases. The flow may be from 2 - 60 L/min depending on the patient interface. HFT150 is used in hospital and professional healthcare environments.	The AIRVO 2 humidifier is for the treatment of spontaneously breathing patients who would benefit from receiving high flow warmed and humidified respiratory gases. This includes patients who have had upper airways bypassed. The flow may be from 2 - 60 L/min depending on the patient interface. The AIRVO 2 is for patients in hospitals and long-term care facilities.	The indications for use are substantially equivalent. The devices are indicated to deliver humidified respiratory gases to spontaneously breathing patients.

TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE:

A technological comparison table is provided below that compares the subject device and predicate device:

Functionality	HFT150 (Subject Device – K233707)	AIRVO 2 Series Humidifier (Primary Predicate Device – K131895)	Assessment of Differences
Flow range	2 – 60 L/min	2 – 60 L/min	Equivalent: The HFT150 is within the range of the predicate
Oxygen input	< 60 L/min (internally regulated via software and a flow sensor)	< 60 L/min	Identical

Functionality	HFT150 (Subject Device – K233707)	AIRVO 2 Series Humidifier (Primary Predicate Device – K131895)	Assessment of Differences
Oxygen Range	21 to 100% O2 via Oxygen module	25 to 95 % O2	Equivalent: The HFT150 has a slightly larger range, and this difference does not impact safety or performance specifications
Design	Integrated blower and humidifier with chamber and heated breathing tube	Integrated blower and humidifier with Integrated blower and humidifier with chamber and heated breathing tube	Similar
Energy source	Electrical from mains to power blower and heating	Electrical from mains to power blower and heating	Identical
Temperature setting	31ºC – 37ºC	31ºC, 34ºC, 37ºC	Identical
Operating principle	Delivery of humidified Air/02 at constant flow to the patient	Delivery of humidified Air/02 at constant flow to the patient	Identical
Patient interface	Nasal cannula only	Nasal cannula, tracheostomy direct connection, face mask	Similar
Alarms	Audible and visual for Temperature, Flow and Oxygen Fraction	Audible and visual for Temperature, Flow and Oxygen Fraction	Identical
User interface	User set point adjustment via rotary encoder knob or pressing color LCD touch screen for temperature and flow	User set point adjustment via menu system on color display for temperature and flow	Equivalent: The difference with user adjustment settings does not impact safety or performance.
Display	LCD display	LED display for Temperature, Flow, Oxygen Fraction	Similar
Control	Software control using feedback sensors with hardware back ups	Software control using feedback sensors with hardware backups	Identical
Integrated Pulse Oximetry	Nonin Xpod 3012LP Optional feature provided for user convenience so users do not have to use a separate, standalone pulse oximetry device.	Not included	Different: Refer to the Reference Device comparison table below.
Transport mode	Limits power to flow only	Limits power to flow only	Identical

A technological comparison is provided below between the subject device and reference device:

Functionality	HFT150 (Subject Device – K233707)	ApneaLink Air (Reference Device K143272)	HVT 2.0 Reference Device K203357)	Assessment of Differences
Integrated Pulse Oximetry	Nonin Xpod 3012LP Optional feature provided for user convenience so users do not have to use a separate, standalone pulse oximetry device.	Nonin Xpod 3012LP	N/A	Identical technology: This additional feature is the same as the reference device, ApneaLink Air (cleared in K143272). This additional feature does not impact safety or performance.
Patient Contacting Materials	Externally communicating, tissue, prolonged duration	N/A	Externally communicating, tissue, prolonged duration	Identical: both devices have the same duration of contact.

SUBSTANTIAL EQUVALENCE DISCUSSION:

The subject device, HFT150, is substantially equivalent in technology, design and function to the predicate device, AIRVO 2 Series Humidifier cleared under K131895. The minor differences between predicate and subject devices are identified in the table above and are described further below.

Both the HFT150 and the predicate device support the delivery of oxygen flow up to 60 L/min. The subject device utilizes an internal mechanism for oxygen flow delivery. The predicate device utilizes an external mechanism for oxygen flow delivery.

Both the HFT150 and the predicate device support a nasal cannula patient interface. The predicate device also supports a tracheotomy and mask interface.

The HFT150 utilizes both a rotary control knob and LCD touch screen for selecting device settings. The predicate device utilizes hard keys for selecting device settings.

The HFT150 provides users the option of an integrated Nonin Xpod 3012LP for SpO2% and Pulse Rate display and alarms for low SpO2%, high SpO2%, High Pulse Rate, and Low Pulse Rate. Although both the subject device and predicate device provide supplemental oxygen, the predicate device does not provide an integrated Pulse Oximetry option. For either the subject device or predicate device, the user may choose to use an external, standalone pulse oximetry device. As such, this submission includes the reference device, ApneaLink Air (K143272), which also utilizes the same well-established Nonin Xpod 3012LP technology. Additionally, a second

reference device, HVT 2.0 (K203357), was added to establish the duration of patient contacting materials as externally communicating, tissue, prolonged duration.

The above differences between the HFT150 subject device and the AIRVO 2 Series Humidifier do not impact substantial equivalency.

TESTING SUMMARY:

Comprehensive testing was conducted to verify and validate that the HFT150 meets specified requirements and is substantially equivalent to the predicate device, AIRVO 2 Series Humidifier. The HFT150 was subjected to verification and validation testing according to the following standards to demonstrate that it performs as intended:

- Safety testing in accordance with IEC 60601-1:2012+AMD1:2012+AMD2:2020, Medical Electrical Equipment – part 1: General requirements for basic safety and essential performance
- EMC testing in accordance with IEC 60601-1-2:2014 ED. 4.0, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances- Requirements and tests
- Biocompatibility testing in accordance with:
    - ISO 18562-1:2017, Biocompatibility Evaluation of Breathing Gas Pathways in Healthcare Applications – Evaluation and testing within a risk management process
    - ISO 18562-2:2017, Biocompatibility Evaluation of Breathing Gas Pathways in Healthcare Applications – Tests for emissions of particulate matter
    - ISO 18562-3:2017, Biocompatibility Evaluation of Breathing Gas Pathways in Healthcare Applications – Test for emissions of volatile organic compounds (VOCs)
    - ISO 10993-1:2018, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
    - ISO 10993-5:2009, Biological Evaluation of Medical Devices - Part 5: Tests for In Vitro Cytotoxicity
    - ISO 10993-10:2021, Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization
    - ISO 10993-11:2017, Biological evaluation of medical devices – Part 11: Tests for systemic toxicity
    - ISO 10993-17:2002, Biological evaluation of medical devices – Part 17: Establishment of allowable limits for leachable substances
    - ISO 10993-23:2021, Biological evaluation of medical devices – Part 23: Tests for irritation

- Particular Requirements testing in accordance with ISO 8185:2007, Respiratory track humidifiers for medical user – Particular requirements for respiratory humidification systems; and 80601-2-74:2017, Particular requirements for basic safety and essential performance of respiratory humidifying equipment
- Device life testing
- Shelf life testing
- Software Verification and Validation Testing in accordance with 21 CFR 820.30, the FDA guidance document, *General Principles of Software Validation*, and the FDA guidance document, *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*.

CONCLUSION:

The information provided in this premarket notification established that the subject device, HFT150, and the predicate device, AIRVO 2 Series Humidifier, are substantially equivalent in comparison to indications for use, design, technology and performance.