January 16, 2026

Flexicare Medical Limited.
Rebecca Funston
Director of Regulatory Affairs and Quality Assurance
Cynon Valley Business Park Mountain Ash. CF45 4ER.
Rhondda Cynon Taf, Wales CF45 4ER
United Kingdom

Re: K251448
Trade/Device Name: FL-10000U Respiratory Humidifier
Regulation Number: 21 CFR 868.5450
Regulation Name: Respiratory Gas Humidifier
Regulatory Class: Class II
Product Code: BTT
Dated: May 9, 2025
Received: December 11, 2025

Dear Rebecca Funston:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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, Respiratory Devices Team
DHT1C: Division of Sleep Disordered
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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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K251448

Device Name
FL-10000U Respiratory Humidifier

Indications for Use *(Describe)*
The Flexicare FL-10000U Respiratory Humidifier is intended to warm and add humidity to gases delivered to patients requiring mechanical ventilation or positive pressure breathing assistance via an endotracheal tube or face mask. For use by trained personnel only within a hospital/institutional environment. This device is intended to be used with the Flexicare Autofill Humidification Chamber and Flexicare Heated Wire Breathing Circuit.

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.

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510(k) Summary

(K251448)

Prepared in accordance with the requirements of 21 CFR Part 807.92

Prepared Date: 2026/01/15

1. Submission sponsor

Name: Flexicare Medical Limited
Address: Cynon Valley Business Park Mountain Ash. CF45 4ER. United Kingdom
Contact person: Rebecca Funston
Title: Director of Regulatory Affairs and Quality Assurance
Tel: +44 (0)1443 474647

2. Subject Device Information

Trade/Device Name	FL-10000U Respiratory Humidifier
Common Name	Respiratory Humidifier
Regulatory Class	Class II
Classification	21 CFR 868.5450 / Respiratory Gas Humidifier / BTT
Product code	BTT
Submission type	Traditional 510(K)

3. Predicate Device

No.	Device name and model	510(K) number	Manufacturer
Predicate device	Flexicare FL-9000U Respiratory Humidifier Base	K161314	Flexicare Medical Limited

4. Device Description

FL-10000U is an electrically powered Respiratory Humidifier that actively conditions the inspired respiratory gases delivered to ventilated patients and those receiving respiratory support. It is used as part of a complete system including a Humidification Chamber and either a heated wire breathing system.

FL-10000U Respiratory Humidifier is used with patients who require mechanical ventilation or positive pressure breathing assistance via an endotracheal tube and/or face mask.

The heater plate warms the water in the Humidification Chamber installed on to the top of the device. Gases are warmed and gain humidity in the form of water vapor as they travel along the breathing circuit on the to the patient.

5. Intended use & Indication for use

The Flexicare FL-10000U Respiratory Humidifier is intended to warm and add humidity to gases delivered to patients requiring mechanical ventilation or positive pressure breathing assistance via an endotracheal tube or face mask. For use by trained personnel only within a hospital/institutional environment. This device is intended to be used with the Flexicare Autofill Humidification Chamber and Flexicare Heated Wire Breathing Circuit.

6. Comparison to the Predicate Device

Table 1: Subject device FL-10000U Respiratory Humidifier Base and Predicate Comparison Table

	Subject Device FL-10000U Respiratory Humidifier Base	**Flexicare's FL-9000U Respiratory Humidifier Base**	**Comparison**
510(k)	Unknown	K161314	-
Indications for use	The Flexicare FL-10000U Respiratory Humidifier Base is intended to warm and add humidity to gases delivered to patients requiring mechanical ventilation or positive pressure breathing assistance via an endotracheal tube or face mask. For use by trained personnel only within a hospital/institutional environment. This device is intended to be used with the Flexicare Autofill Humidification Chamber and Flexicare Heated Wire Breathing Circuit.	The Flexicare FL-9000U Respiratory Humidifier Base is intended to warm and add humidity to gases delivered to patients requiring mechanical ventilation or positive pressure breathing assistance via an endotracheal tube or face mask. For use by trained personnel only within a hospital/institutional environment. This device is intended to be used only with the Flexicare Heated Wire Breathing System and Flexicare Autofill Humidification Chamber.	Same
Product Code	BTT	BTT	Same
Regulation No.	21 CFR 868.5450	21 CFR 868.5450	Same
Classification	Class II	Class II	Same
Supplied/Use	Re-usable	Re-usable	Same
Principle of operation	The device has two heating control units and two	The device has two heating control units and	Same

	temperature sensors respectively. Water within a humidification chamber is heated by the device's heating plate and this temperature is controlled by the device with the use of temperature probes. Dry medical gases passing through the chamber gain increased humidity and heat. The supplied Heated wire adaptors supply current to heated wires within breathing tubes that maintain gas temperature travelling to patient. Temperature probes measurement temperature and device controls chamber temperature to achieve desired gas warmth and humidify for patient.	two temperature sensors respectively. Water within a humidification chamber is heated by the device's heating plate and this temperature is controlled by the device with the use of temperature probes. Dry medical gases passing through the chamber gain increased humidity and heat. The supplied Heated wire adaptors supply current to heated wires within breathing tubes that maintain gas temperature travelling to patient. Temperature probes measurement temperature and device controls chamber temperature to achieve desired gas warmth and humidify for patient.	
Structure and operation	The product consists of FL-10000U Respiratory Humidifier, Heated wire adaptor leads (single & dual) and Temperature sensor leads.	The product consists of FL9000U Respiratory humidifier, Heated wire adaptor leads (single & dual) and Temperature sensor leads.	Same
Mode of operation	Device does not have patient contact. During use it is located between the ventilator and breathing system (between ventilator and patient).	Device does not have patient contact. During use it is located between the ventilator and breathing system (between ventilator and patient).	Same
Scope of patient	Device intended for patients requiring mechanical ventilation,	Device intended for patients requiring mechanical ventilation,	Same

	positive pressure breathing support or other respiratory support requiring controlled heat and humidity	positive pressure breathing support or other respiratory support requiring controlled heat and humidity	
Electric lightning protection	Class I	Class I	Same
Applied part	Type B	Type B	Same
Drip proof	IPX 1	IPX 1	Same
Target population	Any patient requiring active humidification	Any patient requiring active humidification	Same
Housing material	Polycarbonate	Polycarbonate	Same
Temp sensing	YSI	YSI	Same
Heating Method	Pass over	Pass over	Same
Heated Wire control on/off	Yes	Yes	Same
Single/dual/non heated wire compatible	Yes	Yes	Same
Dimensions	156mm × 170mm × 130mm	156mm × 170mm × 130mm	Same
Weight	2.9kg	2.9kg	Same
Supply frequency	50/60 Hz	50/60 Hz	Same
Supply voltage	115V~	115V~	Same
Supply current	2.0 A max at 115V~	2.0 A max at 115V~	Same
Heater plate	150 W	150 W	Same
Heater plate over temperature cutout	115 ± 3°C	115 ± 3°C	Same
Safety cutoff software	110°C	110°C	Same
Heater Wire	22V~, 2.73A, 60W, 50/60Hz	22V~, 2.73A, 60W, 50/60Hz	Same
Temperature control settings (heater wire)			

Airway	Invasive: Default: 40°C, Range: 38-40°C Non-invasive: Default: 34°C, Range: 31-34°C	Invasive: Default: 40°C, Range: 36-40°C Non-invasive: Default: 34°C, Range: 31-35°C	Similar
Chamber outlet	Invasive: Default:37°C, Range: 35-37°C Non-invasive: Default: 31°C, Range: 30-34°C	Invasive: Default: 37°C Range: 34-40°C Non-invasive: Default: 31°C Range: 31-35°C	Similar
Alarm Parameters			
	High Humidity Alarm		
Alarm parameter	Airway: High alarm Chamber: High alarm / Low alarm	Airway: High alarm / Low alarm Chamber: High alarm / Low alarm	Similar
Display temperature of 41℃	Yes	Yes	Same
Airway Temperature exceeds 43℃	Yes	Yes	Same
	Low Humidity Alarm		
60 minutes @ 34.5 °C	Yes	Yes	Same
10 minutes @ 29.5 °C	Yes	Yes	Same
Sound Pressure Level	Alarms exceed 50 dBA @ 1m	Alarms exceed 50 dBA @ 1m	Same
Performance			
Recommended ambient Temperature range	18 - 26°C	18 - 26°C	Same
Recommended Flow range	Invasive: Min 1.5 lpm at a PEEP ≥ 3 cmH_2O Non-Invasive: Max 60 lpm	Invasive: Up to 60 L/min Non-invasive: Up to 120 L/min	Different
Humidity	Invasive: >33mg/L	Invasive: >33mg/L	Same

performance	Non-invasive: >10mg/L	Non-invasive: >10mg/L	
Warm-up time	Less than 30 minutes	Less than 30 minutes	Same
Standard and Approvals	IEC 60601-1 IEC 60601-1-2 ISO 80601-2-74 ISO 10993-1 IEC 62366-1 IEC 62304 ISO 3744 IEC 60529	EN 60601-1 EN 60601-1-2 EN ISO 8185 EN ISO 10993-1,3,5,6,10 EN 62366 EN 62304 ISO 3744 BS EN 60529	Equivalent, ISO 8185 is replaced by newest version ISO 80607-2-74

7. Non-clinical Data

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

Biocompatibility testing

Biocompatibility of the subject device was evaluated in accordance with the FDA guidance “Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" and International Standard ISO 10993-1 “Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process,” and ISO 18562-1” Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 1: Evaluation and testing within a risk management process” as recognized by FDA, FDA's guidance document on Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process",2023. Testing of the subject device demonstrates an appropriate biocompatibility profile for the device.

Electrical safety, electromagnetic compatibility (EMC) and Alarms

Electrical safety and EMC testing were conducted on the subject device. The system complies with the ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021] for safety and the IEC 60601-1-2:2014 + AMD1:2020 Ed 4.1 for EMC. Alarms testing was performed in accordance with IEC 60601-1-8:2006+AMD1:2012+AMD2:2020.

Bench performance testing

Performance testing was conducted to demonstrate substantial equivalence including:

- ISO 80601-2-74 Second edition 2021-07 Medical electrical equipment - Part 2-74:

Particular requirements for basic safety and essential performance of respiratory humidifying equipment

8. Clinical study

Not applicable.

9. Conclusion

Performance testing and compliance with voluntary standards demonstrate that the subject device is substantially equivalent to the predicate device.