DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 6, 2016

Dave Yungvirt
Third Party Review Group, LLC (TPRG)
The Old Station House
24 Lackawanna Place
Millburn, NJ 07041

Re: K161314
Trade/Device Name: Flexicare FL-9000U Respiratory Humidifier Base
Regulation Number: 21 CFR 868.5450
Regulation Name: Respiratory gas humidifier
Regulatory Class: Class II
Product Code: BTT
Dated: June 16, 2016
Received: June 17, 2016

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. 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); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

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Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
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General Hospital, Respiratory,
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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)*
K161314

Device Name
Flexicare FL-9000U Respiratory Humidifier Base

Indications for Use *(Describe)*

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.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) Summary

510(k) Sponsor, Contact Person and Date Summary Prepared:

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Summary prepared on: July 4th, 2016

Device Name:

Trade Name: Flexicare FL-9000U Respiratory Humidifier Base

Common/Usual Name: Respiratory Gas Humidifier

Classification Name: Respiratory Gas Humidifier: 21 CFR 868.5450

Product Codes: BTT (Respiratory Gas Humidifier)

There have been no prior submissions for the device included within this submission.

Legally Marketed Equivalent Device:

FL-9000U Respiratory Humidifier Base is substantially equivalent to Fisher & Paykel's MR850 Respiratory Humidifier cleared under K073706.

Device Description:

The Flexicare FL-9000U Respiratory Humidifier Base is for use as part of a complete system to provide warmed and humidified inspired respiratory gases to ventilated adult patients and those receiving respiratory support, as part of a complete system including a Humidification Chamber and either a heated wire breathing circuit or limb, or a non-heated breathing circuit or limb.
The Flexicare FL-9000U Respiratory Humidifier Base is a non-sterile medical electrical device which when in use forms part of an actively humidified respiratory humidification system. The Flexicare FL-9000U features a heater plate that allows a humidification chamber containing a volume of water to secure in place above it. The Flexicare FL-9000U heats the water within a humidification chamber and provides current to heated wires within Heated Wire Breathing System (if using a heated system) to warm and humidify gases to be administered to the patient. The Flexicare FL-9000U Respiratory Humidifier Base is provided with temperature probe leads that connect to the patient end and humidification chamber end of a breathing system. These probes feedback to the FL-9000U which automatically adjusts heat and current accordingly to maintain the set gas temperature.
When in use the Flexicare FL-9000U Respiratory Humidifier Base has no contact with the patient. The probe tip of the temperature probe lead accessory contacts breathing gases that

are to be delivered to the patient and is the only component of the device/its accessories with contact of this nature.
The Flexicare FL-9000U Respiratory Humidifier Base is mains powered (115V), intended for use within a hospital environment and intended for any patient population where active humidification is required.

Intended Use:

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.

Substantial Equivalence:

Flexicare's FL-9000U Respiratory Humidifier Base has the same intended use as the predicate device, Fisher & Paykel's MR850 Respiratory Humidifier.
Flexicare's FL-9000U Respiratory Humidifier Base and the predicate device are reusable medical electrical devices. Supplied in one variation for all patient populations.

Neither manufacturer's devices are life supporting or life sustaining.

Patient Contact: – FL-9000U Respiratory Humidifier Base has no contact with the patient. The Temperature probe lead accessory contacts breathing gases that are to be delivered to the patient (externally communicating). The material of this component has been subject to biocompatibility testing, and amounts to only 0.02% of total surface area when used in conjunction with an Adult Heated Wire Breathing System.

Flexicare's FL-9000U Respiratory Humidifier Base and the predicate devices by Fisher & Paykel both include one component that has gas pathway contact – the temperature probe present on supplied temperature probe lead.

Flexicare's FL-9000U Respiratory Humidifier Base and the predicate devices by Fisher & Paykel both require software to operate/function.

Flexicare's FL-9000U Respiratory Humidifier Base and the predicate devices by Fisher & Paykel are both electronically powered devices (115V).

Flexicare's FL-9000U Respiratory Humidifier Base and the predicate devices by Fisher & Paykel are both supplied non-sterile.

Both manufacturers' devices are able to be used with industry standard devices such as humidification chambers and breathing systems.
Flexicare's FL-9000U Respiratory Humidifier Base and the predicate devices by Fisher & Paykel are both are designed for the same intended use in the same intended conditions. During comparison testing it was determined that there were no invasive components in either of the manufacturer's devices.

Both manufacturers' device's feature an LCD display, depressible front lip to secure a humidification chamber, invasive/non-invasive mode selecting button, are mains powered (115v) and are supplied with cables to connect to a Heated Wire Breathing System.
Both manufacturers' device's feature a polycarbonate based rigid housing.

Both manufacturers' device's feature a fixed US mains (115V) power cable and plug.

The housing of Flexicare's FL-9000U Respiratory Humidifier Base is beige, with remaining components being white or grey. Labelling on device housing is blue and white in-line with Flexicare branding.

Any differences in color between the Flexicare device and the predicate device is by manufacturer's aesthetics choice/ branding, and is not related to intended use or performance of device.

Both manufacturer's devices are supplied with a mains power cable, single heated wire adaptor lead, dual heated wire adaptor cable and a temperature probe lead to connect to a single or dual Heated Wire Breathing System.

Both Flexicare's FL-9000U Respiratory Humidifier Base and the predicate device can be used with Dual Heated Wire Breathing Systems, Single Heated Wire Breathing Systems and Non- Heated Wire Breathing Systems in both invasive and non-invasive modes.

Neither manufacturer's devices are in vitro diagnostic devices.

<u>Accessories</u>

Flexicare's FL-9000U Respiratory Humidifier Base is supplied with the following compatible accessories:

- **FL9000-01U** - Single Heated Wire Adaptor Lead; the Single Heated Wire Adaptor Lead is used to supply electrical current from the FL-9000U Respiratory Humidifier Base to a Single Heated Wire Breathing System (if a heated breathing system is used).

- **FL9000-02U** - Dual Heated Wire Adaptor Lead; the Dual Heated Wire Adaptor Lead is used to supply electrical current from the FL-9000U Respiratory Humidifier Base to a Dual Heated Wire Breathing System (if a heated breathing system is used).

- **FL9000-03U** - Temperature Probe Lead; the Temperature Probe Lead is used to monitor the temperature at the chamber and at the patient end of the breathing system. Temperature measurements are fed back to the FL-9000U Respiratory Humidifier Base which automatically adjusts output accordingly to maintain the temperature within the breathing system at the set parameters.

Flexicare's FL-9000U Respiratory Humidifier Base is compatible with, yet not supplied with, the following accessories:

- Flexicare Heated Wire Breathing Systems. Cleared under K150900

- Flexicare Autofill Humidification Chambers. Cleared under K150900

Substantial equivalence comparison table – Respiratory Humidifier

Flexicare's FL-9000U Respiratory Humidifier Base is substantially equivalent to MR850 Respiratory Humidifier manufactured by Fisher & Paykel (510(k) K073706).

The Table below shows the similarities and differences between Flexicare's FL-9000U Respiratory Humidifier Base and the predicate device manufactured by Fisher & Paykel.

Characteristic compared	Flexicare's FL-9000U Respiratory Humidifier	Fisher & Paykel MR850 Respiratory Humidifier
510K	K: Unknown	K:073706
Device Description	FL-9000 is a Dual Servo Controlled Heated Respiratory Humidifier, controlling both Airway & Chamber temp	MR850 is a Dual Servo Controlled Heated Respiratory Humidifier, controlling both Airway & Chamber temp
Intended use	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.	The Fisher & Paykel Healthcare MR850 humidifier is intended to be used to warm and add humidity to gases delivered to patients requiring mechanical ventilation or positive pressure breathing assistance or general medical gases. The heated-wire breathing circuits are intended as conduits of breathing gas for ventilation of patients, and to maintain the temperature of humidified inspired gas, to reduce condensation. They are accessories for the Fisher & Paykel Healthcare MR850 Respiratory Gas Humidifier. The RT130 is used for flow rates between 0.3 and 4 L/min, and the RT131 is for flow rates greater than 4 L/min, for neonatal patients. Source: Fisher & Paykel K073706 clearance letter.
Principle of operation	The device has two heating control units and 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.	The device has two heating control units and 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-9000U Respiratory humidifier, Heated wire adaptor leads (single & dual) and Temperature sensor leads.	The product consists of MR850 Respiratory humidifier, Heated wire adaptor leads (single & dual) and Temperature sensor leads.

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).
Scope of patient		Device intended for patients requiring mechanical ventilation, positive pressure breathing support or other respiratory support requiring controlled heat and humidity	Device intended for patients requiring mechanical ventilation, positive pressure breathing support or other respiratory support requiring controlled heat and humidity
Electric lightning protection		Class I	Class I
Applied part		Type B	Type B
Drip proof		IPX 1	IPX 1
Target population		Any patient requiring active humidification	Any patient requiring active humidification
Housing material		Polycarbonate	Polycarbonate
Temp sensing		YSI	YSI
Heating Method		Pass over	Pass over
Heated Wire control on/off		Yes	Yes
Single/dual/non heated wire compatible		Yes	Yes
Dimensions		156mm × 170mm × 130mm	140mm × 173mm × 135mm
Weight		2.9kg	2.8kg
Supply frequency		50/60 Hz	50/60 Hz
Supply voltage		115V~	115V~
Supply current		2.0 A max at 115V~	2.0 A max at 115V~
Heater plate		150 W	150 W
Heater plate over temperature cutout		115 ± 3°C	118 ± 6°C
Safety cutoff software		110°C	110°C
Heater Wire		22V~, 2.73A, 60W, 50/60Hz	22V~, 2.73A, 60W, 50/60Hz
Temperature control settings (heater wire)			
Airway	Invasive	Default: 40°C Range: 36-40°C	Default: 40°C Range: 35-40°C (Versions 7.22)
	Non-invasive	Default: 34°C Range: 31-35°C	Default: 34°C Range:28-34°C (Versions 7.22)
Chamber outlet	Invasive	Default: Range: 34-40°C	Default: Range: 35.5-42°C (Versions 7.22)
	Non-invasive	Default: Range: 31-35°C	Default: Range: 31-36°C (Versions 7.22)
Temperature control settings (non-heater wire)			
Airway	Invasive	37°C (Range 36-38°C)	37°C
Chamber outlet	Non-invasive	31°C (Range 30-32°C)	31°C

Display	4 digit 14 mm 14 segment LED		3 digit 14 mm 7 segment LED	
Display range	05 - 80°C		10 - 70°C	
Accuracy	± 0.3°C		± 0.3°C	
Alarm Parameters				
High Humidity Alarm				
Alarm parameter	Airway: High alarm / Low alarm Chamber: High alarm / Low alarm		High Humidity Alarm Low Humidity Alarm	
Display temperature of 41°c	Yes		Yes	
Airway Temperature exceeds 43°C	Yes		Yes	
Low Humidity Alarm				
60 minutes @ 34.5 °C	Yes		Yes	
10 minutes @ 29.5 °C	Yes		Yes	
Sound Pressure Level	Alarms exceed 50 dBA @ 1m		Alarms exceed 50 dBA @ 1m	
Performance				
Recommended ambient Temperature range	18 - 26°C		18 - 26°C	
Recommended Flow range	Invasive	Non-invasive	Invasive	Non-invasive
	Up to 60 L/min	Up to 120 L/min	Up to 60 L/min	Up to 120 L/min
	Refer to Humidity Test Report (NO. HSO-VH-2600A-2015-01,1)			
Humidity performance	Invasive	Non-invasive	Invasive	Non-invasive
	>33mg/L	>10mg/L	>33mg/L	>10mg/L
Warm-up time	Less than 30 minutes		Less than 30 minutes	
Standard and Approvals	EN 60601-1:2006 EN 60601-1-2:2007 EN ISO 8185:2009 EN ISO 10993-1,3,5,6,10 EN 62366:2008 EN 62304:2006 ISO 3744:2010 BS EN 60529:1992+A2:2013		IEC 60601-1 EN 60601-1 IEC 60601-1-2 EN 60601-1-2 EN ISO 8185:2009	
Non-clinical Test Results	Verification tests were performed to establish the safety and efficacy of Flexicare's FL-9000U Respiratory Humidifier. These Non-clinical tests included Dimensions and weight measurement, power supply, heater plate capacity, heater wire power supply, display range, display accuracy, alarm parameters, sound pressure level, humidification output, Electromagnetic Capability, Electrical Safety and IPX 1 testing. Testing demonstrated that the relevant features, design and performance of each manufacturer's device are substantially equivalent.			
Conclusion	Flexicare's FL-9000U Respiratory Humidifier Base is considered to be substantially equivalent to the Fisher & Paykel MR850 Respiratory Humidifier. The comparison of features, performance, materials and intended use demonstrate that Flexicare's FL-9000U Respiratory Humidifier Base is as safe and effective as the predicate device for its intended purpose.			
Accessories				
Single Heated Wire Adaptor Lead				
Connector (Machine end)	4-Pin Connector		4-Pin Connector	
Connector (Patient end)	2 pin S-type		2 pin S-type	
Type/configuration	Single		Single	

Supplied	Yes	Yes
Dual Heated Wire Adaptor Lead		
Connector (Machine end)	4-Pin Connector	4-Pin Connector
Connector (Patient end)	2 pin S-type 2 pin clover-type	2 pin S-type 2 pin clover-type
Type/configuration	Dual	Dual
Supplied	Yes	Yes
Temperature Probe Lead		
Length	192 cm	207 cm
Number of probes	2	2
Probe location	Chamber, Patient end	Chamber, Patient end
Function	Airway Temp./ Chamber Temp. Measure	Airway Temp./ Chamber Temp. Measure
Supplied	Yes	Yes

Summary of performance Testing: Flexicare's FL-9000U Respiratory Humidifier Base has been evaluated in accordance with standards listed in table:

Test	Standard / Pre-Determined Acceptance Criteria	Outcome
Dimensions & weight	Comparison test	Substantially equivalent
Power Supply voltage	Comparison test	Substantially equivalent
Power Supply frequency	Comparison test	Substantially equivalent
Power Supply current	Comparison test	Substantially equivalent
Heater plate capacity	Comparison test	Substantially equivalent
Heater Wire Supply Voltage	Comparison test	Substantially equivalent
Heater Wire Supply current	Comparison test	Substantially equivalent
Heater Wire Supply resistance	Comparison test	Substantially equivalent
Heater Wire Supply power	Comparison test	Substantially equivalent
Display range	Comparison test	Substantially equivalent
Display accuracy	Comparison test	Substantially equivalent
High humidity alarm parameters	Comparison test	Substantially equivalent
Low humidity alarm parameters	Comparison test	Substantially equivalent
Sound pressure level	Comparison test	Substantially equivalent
Cytotoxicity, Irritation, Sensitization, Systemic Toxicity, Genotoxicity, Implantation & Sub-Acute Toxicity.	10993-10:2010 10993-5:2009 10993-3:2014 10993-6:2009	Pass
Requirements for respiratory humidification systems	ISO 8185:2009	Pass
Electromagnetic capability & Electrical safety testing	BS EN 60601-1:2006 BS EN 60601-1-2:2007 IEC 60601-1:2005 +CORR.1:2006 CORR. 2:2007	Pass
Enclosure testing – IP rating (IPX1)	IEC 60529 Edition 2.2: 2013	Pass

Flexicare's FL-9000U Respiratory Humidifier Base has been evaluated for performance within K161314 with the compatible accessories noted in this 510(k) summary, including those supplied with the FL-9000U and those not supplied, cleared under K150900.

Consensus Standards

ISO 8185 and ISO 5356-1 are recognized consensus standards for devices classified through FDA product code BTT.
However, ISO 5356 (and its associated guidance documents) is not applicable to Flexicare's FL-9000U Respiratory Humidifier. ISO 5356 is the internationally recognized standard for conical connectors present within anesthetic and respiratory medical devices.
Neither Flexicare's FL-9000U Respiratory Humidifier, its supplied accessories nor the predicate device manufactured by Fisher & Paykel have conical connectors included within their designs.
Conical connectors are present on related equipment devices such as Humidification Chambers and Heated Wire Breathing Systems. However, in Flexicare's case these devices have been cleared separately under K150900, and are not supplied with the FL-9000U Respiratory Humidifier.
The MR850 predicate device manufactured by Fisher & Paykel is also not supplied with any related equipment that include conical connectors.

The Flexicare FL-9000U Respiratory Humidifier Base passed the performance testing when tested against methods and criteria from relevant FDA Recognized standards. The results of this testing show that The Flexicare FL-9000U Respiratory Humidifier Base passes all performance & safety tests and performs at least as well as the marketed predicate device.

Although very similar in design and function there are some differences, as described below, between the Flexicare FL-9000U Respiratory Humidifier Base and the predicate device from Fisher & Paykel.

Differences:

- The Flexicare FL-9000U Respiratory Humidifier Base has a 4 digit 14 segment LED display whilst the Fisher and Paykel device has a 3 digit 7 segment LED display. This does not cause an advantage in performance for Flexicare's device, but allows for more versatile/detailed display.

- The Flexicare FL-9000U Respiratory Humidifier Base has text definitions adjacent to LED warning lights that illuminate during fault conditions. This allows user to immediately understand the reason for alarm. The Fisher & Paykel MR850 does not have this text.
- The Flexicare FL-9000U Respiratory Humidifier Base also has an LED indicator with a symbol for "Refer to instructions for use" adjacent to it which illuminates also during fault conditions.

- Another difference between Flexicare's device and its predicate device from Fisher & Paykel is the color of the humidification chamber securing area at the top of the device, where Flexicare's is white in color and F&P's is light blue in color. However, these differences in color do not affect the safety and/or effectiveness of either manufacturer's devices and are due to individual company branding/marketing.

Conclusion: The overall conclusion from the comparison testing is that Flexicare's FL-9000U Respiratory Humidifier Base is considered to be substantially equivalent to that of the predicate device.