DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 23, 2016

Flexicare Medical Ltd.
% Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street, NW
Buffalo, Minnesota 55313

Re: K160540
Trade/Device Name: Flexicare Neonatal Heated Wire Breathing Systems
Regulation Number: 21 CFR 868.5270
Regulation Name: Breathing System Heater
Regulatory Class: Class II
Product Code: BZE, BTT
Dated: May 27, 2016
Received: June 8, 2016

Dear Mark Job:

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" (21CFR 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,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Division 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)*
K160540

Device Name
Flexicare Neonatal Heated Wire Breathing Systems

Indications for Use *(Describe)*

Flexicare Neonatal Heated Wire Breathing Systems are intended for use to connect a patient's airway to a Ventilator and Humidification Chamber as part of a complete system to provide warmed and humidified inspired respiratory gases to ventilated patients and those receiving respiratory support. Intended for Neonatal patients within a hospital environment. Compatible with Fisher & Paykel MR850 Respiratory Gas Humidifier. Available in Neonatal (038-33-201U) size. For flow rates >4L/min.

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)*

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

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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)*

Device Name
Flexicare Autofill Humidification Chamber

Indications for Use *(Describe)*

Humidification Chambers are intended for use to hold water required to humidify the air being delivered to patients. Intended for any patient requiring active humidification within a hospital environment.

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)

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510(k) Summary

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

Flexicare Medical Limited
Cynon Valley Business Park
Mountain Ash, Mid. Glamorgan
CF45 4ER. United Kingdom

Joel Biddle
Senior Compliance Engineer
Telephone: 00 44 1443 474 647
Fax: 00 44 1443 474 222

Summary prepared on: May 27th, 2016

Device Name:

Trade Name: Flexicare Neonatal Heated Wire Breathing Systems

Common/Usual Name: Heated Breathing System

Classification Name: Breathing System Heater: 21 CFR 868.5270

Product Codes: BZE (breathing system heater) and BTT (respiratory gas humidifier).

Legally Marketed Equivalent Device:

Flexicare's Neonatal Heated Wire Breathing Systems are substantially equivalent to Fisher & Paykel's Neonatal RT235 Heated Breathing Circuit cleared under K034026.

Flexicare's Autofill Humidification Chamber is substantially equivalent to Fisher & Paykel's MR290 Autofill Humidification chamber cleared under K934140.

Device Description:

Flexicare Neonatal Heated Wire Breathing Systems are sterile single patient use devices which form part of a respiratory humidification system. In this system the inspiratory limb delivers heated humidified gas to the patient and expiratory limb carries the expired gas away from the patient.
Flexicare Neonatal Heated Wire Breathing Systems are supplied with an Auto-fill Humidification chamber. When in use a Humidification Chamber holds a volume of water and is placed onto a heater unit and fills automatically from a suspended water source.
The air from the ventilator is passed through the Humidification Chamber, gaining heat and humidity. This air is then channeled through the Heated Wire Breathing System to the patient.

The inclusion of a heated wire within the lumen of both the System tubes reduces the amount that the humidified air cools when travelling to/from the patient. This in turn reduces the amount of condensation and water build-up within the System.

Flexicare's Neonatal Heated Wire Breathing Systems are comprised of disposable connectors, tubing and heated wire assemblies. The systems are intended for Neonatal patients.

Intended Use:

Flexicare Neonatal Heated Wire Breathing Systems are intended for use to connect a patient's airway to a Ventilator and Humidification Chamber as part of a complete system to provide warmed and humidified inspired respiratory gases to ventilated patients and those receiving respiratory support. Intended for Neonatal patients within a hospital environment. Compatible with Fisher & Paykel MR850 Respiratory Gas Humidifier. Available in Neonatal (038-33-201U) size. For flow rates >4L/min.

Humidification Chambers are intended for use to hold water required to humidify the air being delivered to patients. Intended for any patient requiring active humidification within a hospital environment.

Substantial Equivalence:

Flexicare's Neonatal Heated Wire Breathing Systems have the same intended use as the predicate device.
Flexicare's Neonatal Heated Wire Breathing Systems and the Predicate device are single patient use devices. Supplied in Neonatal sizes.

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

Patient Contact
Externally Communicating – Tissue contact of permanent duration.

Neither Flexicare's Neonatal Heated Wire Breathing Systems nor the predicate device by Fisher & Paykel require software to operate/function.

Flexicare's Neonatal Heated Wire Breathing Systems & the predicate device require connection to an electronically powered Fisher & Paykel MR850 Respiratory Gas Humidifier.

Flexicare's Neonatal Heated Wire Breathing Systems are supplied sterile in individual EO permeable pouches. Fisher & Paykel's devices are supplied non-sterile in sealed Polybags.

Both devices are able to be used with industry standard devices such as ventilators and catheter mounts.

Both Flexicare's Neonatal Heated Wire Breathing Systems & the predicate device are designed for the same intended use in the same intended conditions.
Both designs consist of components made from injection molded & extruded plastics.
During comparison testing it was determined that there were no invasive components in either of the manufacturer's devices.

The gas delivering tubing of both the Flexicare and predicate device are manufactured from Low density Polyethylene. Both manufacturers' device's feature an inspiratory limb angled

22mm female connector with temperature port. Both manufacturers' device's also feature a Y-piece connector with temperature port at the patient end.
All connectors on both Flexicare and Predicate devices are conical connectors compliant with ISO 5356-1:2004.

Flexicare Neonatal Heated Wire Breathing System tubes are blue and/or colorless with all connectors blue in color except for the angled machine-end connectors which are colorless. The Fisher and Paykel Heated Wire Breathing System tubes are blue and/or colorless with colorless connectors.

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

Both manufacturer's devices are supplied with an automatically filling humidification chamber.

Both Flexicare Neonatal Heated Wire Breathing Systems and Predicate device have 1.6m expiratory tube length breathing tube length.
Flexicare's Neonatal Heated Wire Breathing Systems Inspiratory tube is 1100mm + 300mm in length.
Fisher & Paykel predicate device Inspiratory tube is 1100mm + 360mm in length.

Substantial equivalence comparison table - Neonatal Heated Wire Breathing Systems

Flexicare's Neonatal Heated Wire Breathing Systems are substantially equivalent to RT235 Heated Wire Breathing System manufactured by Fisher & Paykel (510(k) K034026)
The Table below shows the similarities and differences between the Flexicare Medical Neonatal Heated Wire Breathing Systems and Fisher & Paykel predicate device.

Characteristic compared	Flexicare Neonatal Heated Wire Breathing Systems	Predicate Device F&P RT235
510K	K:160540	K:034026
Intended use	Flexicare Neonatal Heated Wire Breathing Systems are intended for use to connect a patient's airway to a Ventilator and Humidification Chamber as part of a complete system to provide warmed and humidified inspired respiratory gases to ventilated patients and those receiving respiratory support. Intended for Neonatal patients within a hospital environment. Compatible with Fisher & Paykel MR850 Respiratory Gas Humidifier. Available in Neonatal (038-33-201U) size. For flow rates >4L/min.	The dual-heated breathing circuits are intended as conduits of breathing gas for ventilation of patients, and to maintain the temperature of humidified inspired gas. The RT236 is used for flow rates between 0.3 and 4 L/min, and the RT235 is for flow rates greater than 4 L/min, for infant patients. Source: K034026 SE letter from FDA
Target population	Neonatal	Neonatal
Indications for use	Instruction leaflet	Instruction leaflet
Environment used	Hospital	Hospital
Product labelling	Heated Wire Breathing System	Heated Wire Breathing System
Volume (ml)	500	375
Tube length (m)	Ins – 1.1m + 300mm extension Exp – 1.66m	Ins – 1.1m + 360mm extension Exp – 1.65m
Wire resistance (ohms)	Ins – 21.6 Exp – 19.2	Ins – 21.8 Exp – 22.9
Tube material and designated diameter	Ins – Corrugated 15mm Exp – Smoothbore 15mm	Ins – Corrugated 15mm Exp – Corrugated 15mm
Rated Flow	>4L.min	>4L.min
Compliance (ml/Kpa)	5.18ML/kPa	3.64ML/kPa
Resistance to flow @ 30 lpm (mb)	2.7	2.1
Compatibility with the environment and other devices.	To be used with Flexicare Autofill Humidification Chamber. Compatible with F & P MR850 Respiratory Gas Humidifier.	To be used with F & P MR290 Humidification Chamber. Compatible with F & P MR850 Respiratory Gas Humidifier.

Active controller	No – Humidifier controlled	No – Humidifier controlled
Energy used and or delivered	Due to the wire resistance, heat is dispersed into the breathing tube lumen. As a result, the air passing through the tubing is warmed whilst travelling to patient, reducing the water condensation in the breathing System. The raising of the gas temperature does not exceed 37ºC	Due to the wire resistance, heat is dispersed into the breathing tube lumen. As a result, the air passing through the tubing is warmed whilst travelling to patient, reducing the water condensation in the breathing System. The raising of the gas temperature does not exceed 37ºC
Sterility	Sterile – Ethylene Oxide Gas	Non-Sterile
Standards Met	ISO 5367 ISO 5356 ISO 8185 IEC 60601-1 ISO 10993 BS EN 556	ISO 5367 ISO 5356 ISO 8185 IEC 60601-1 ISO 10993
Biocompatibility	ISO 10993 compliant	ISO 10993 compliant
Electrical Safety	IEC 60601-1 compliant IEC 60601-1-2 compliant	IEC 60601-1 compliant IEC 60601-1-2 compliant
Non-clinical Test Results	Verification tests were performed to establish the safety and efficacy of Flexicare's 038-33-201U Neonatal Heated Wire Breathing System. These Non-clinical tests included Visual inspection/comparison, Dimensional inspection, Internal Volume, Heated wire resistance, resistance to flow, humidifier start up/compatibility, conical connector compliance, connector strength, leaking, drop testing, tensile strength, tube compliance, humidification output, shelf life verification, Electromagnetic Capability, Electrical Safety and Biocompatibility. Testing demonstrated that the relevant features, design and performance of each manufacturer's device are substantially equivalent.	
Conclusion	Flexicare's 038-33-201U Neonatal Heated Wire Breathing System is considered to be substantially equivalent to the Fisher & Paykel RT235 Breathing Circuit. The comparison of features, performance, materials and intended use demonstrate that Flexicare's 038-33-201U Neonatal Heated Wire Breathing System is as safe and effective as the predicate device for its intended purpose.	

Substantial equivalence comparison table - Autofill Humidification Chamber

Flexicare's Autofill Humidification Chamber is substantially equivalent to MR290 Autofill Humidification Chamber manufactured by Fisher & Paykel (510(k) K934140)
The Table below shows the similarities and differences between the Flexicare Medical Autofill Humidification chamber and Fisher & Paykel predicate device.

Characteristic compared	Flexicare Autofill Humidification Chamber	Predicate Device F&P MR290
510K	K:160540	K:934140
Intended use	Humidification Chambers are intended for use to hold water required to humidify the air being delivered to patients. Intended for any patient requiring active humidification within a hospital environment.	Humidification chambers are intended for use to hold water required to humidify the air being delivered to patients.
Target population	Any patient using a heated humidifier	Any patient using a heated humidifier
Indications for use	Instruction leaflet	Instruction leaflet
Environment used	Hospital	Hospital
Product labelling	Autofill Humidification chamber	Autofill Humidification chamber
Fill Volume (ml)	Full = 292 Max = 114.9	Full = 340 Max = 83.9
Weight (g)	124	109.5
Leakage (ml/min)	No leakage	No leakage
Compliance at empty (ml/Kpa)	5.5	5.5
Resistance to flow @ 60 lpm (mb)	0.1	0.3
Moisture output (mg/l) at 10lpm	46.6	53.9
Compatibility with the environment and other devices.	To be used with Flexicare's Heated Wire Breathing Systems and F & P MR850 Respiratory Gas Humidifier.	To be used with F & P Heated Wire Breathing Systems and F & P MR850 Respiratory Gas Humidifier.
Energy used and or delivered	Electrical energy within heater unit is used to raise the temperature and humidity of the gas delivered to the patient	Electrical energy within heater unit is used to raise the temperature and humidity of the gas delivered to the patient
Sterility	Sterile – Ethylene Oxide Gas	Non-Sterile
Standards Met	ISO 5367 ISO 5356 ISO 8185 IEC 60601-1 ISO 10993 BS EN 556	ISO 5367 ISO 5356 ISO 8185 IEC 60601-1 ISO 10993
Biocompatibility	ISO 10993 compliant	ISO 10993 compliant
Electrical Safety	IEC 60601-1 compliant IEC 60601-1-2 compliant	IEC 60601-1 compliant IEC 60601-1-2 compliant
Non-clinical Test Results	Verification tests were performed to establish the safety and efficacy of Flexicare's Autofill Humidification Chamber. These Non-clinical tests included Visual inspection/comparison, Dimensional inspection, Internal Volume, resistance to flow, conical connector	

	compliance, connector strength, leaking, tensile strength, compliance, humidification output, shelf life verification, Electromagnetic Capability, Electrical Safety and Biocompatibility. Testing demonstrated that the relevant features, design and performance of each manufacturer's device are substantially equivalent.
Conclusion	Flexicare's Autofill Humidification Chamber is considered to be substantially equivalent to the Fisher & Paykel MR290 Humidification Chamber. The comparison of features, performance, materials and intended use demonstrate that Flexicare's Autofill Humidification Chamber is as safe and effective as the predicate device for its intended purpose.

Summary of performance Testing: Flexicare's Neonatal Heated Wire Breathing Systems have been evaluated in accordance with standards listed in table:

Test	Standard / Pre-Determined Acceptance Criteria	Outcome
Visual inspection	Pre-Determined Acceptance Criteria	Pass
Dimensional inspection	Pre-Determined Acceptance Criteria	Pass
System internal volume	Pre-Determined Acceptance Criteria	Pass
Wire resistance	Pre-Determined Acceptance Criteria	Pass
Tubing resistance to flow	Pre-Determined Acceptance Criteria	Pass
MR850 start-up test/ system compatibility check	Pre-Determined Acceptance Criteria	Pass
Means of connection	ISO 5367:2000	Pass
Tubing resistance to flow		
Increase in flow with bending		
Leakage		
Compliance		
Packaging Pouch Integrity	ASTM F1886-09 ASTM F88-09 ASTM F1929-12	Pass
Conical Connector compliance	ISO 5356-1:2004	Pass
Leak testing		
Drop testing		
Cytotoxicity, Irritation, Sensitization, Systemic Toxicity, Genotoxicity, Implantation, Sub-Acute Toxicity, Extractables & Leachables testing.	10993-10:2010 10993-5:2009 10993-3:2014 10993-6:2009 10993-17:2009	Pass
Testing to ISO 5367, temp probe tensile testing, temp port leaking	ISO 8185:2007	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

Device Design Differences:

Although very similar in design and function there are some differences, as described below, between the Flexicare Neonatal Heated Wire Breathing Systems and the predicate devices from Fisher & Paykel.
The Flexicare Neonatal Heated Wire Breathing System has a corrugated inspiratory limb and a smoothbore expiratory limb whilst the Fisher and Paykel device has corrugated limbs for both inspiratory and expiratory.

Another difference between Flexicare's device and its predicate device from Fisher & Paykel is the colour of tubing, connectors and accessories. However, these differences in colour do not affect the safety and/or effectiveness of either manufacturer's devices and are due to individual company branding/marketing.
The overall conclusion from the comparison testing is that Flexicare's Neonatal Heated Wire Breathing Systems are considered to be substantially equivalent to that of the predicate devices.

Testing carried out to evaluate substantial equivalence between Flexicare's devices and the predicate devices captured within K160540 was undertaken in accordance to relevant ISO, ASTM, IEC and BS EN FDA recognized standards.
These standards have been developed and created in conjunction with various committees and regulatory bodies worldwide, and set criteria for the critical elements of a device in terms of function, performance, safety and regulatory compliance.

The testing captured within the summary of testing table above supported the determination of substantial equivalence. This was determined as these tests are mandatory requirements of the standards related to the devices in question, and are the baseline of tests that should be carried out to evaluate the safety of a both a new device of this nature and/or evaluate substantial equivalence against a marketed device.
When tested to methods specified within the listed standards Flexicare's Neonatal Heated Wire Breathing Systems performed passed all testing, and performed at least as well as the marketed predicate devices. This demonstrated not only the compliance of Flexicare's device with relevant standards, but also the similarity of design, function, performance, safety between Flexicare's Neonatal Heated Wire Breathing Systems and the marketed predicate devices.

A number of "non-standard" tests were also conducted to contribute toward the determination of substantial equivalence between Flexicare's Neonatal Heated Wire Breathing Systems and the marketed predicate devices. Being "non-standard", these tests are marked as "Pre-Determined Acceptance Criteria" within the table above and have no set criteria. This testing was conducted to further illustrate similarities between devices that may not have been required to identify within the relevant standards.

Conclusion

Flexicare's 038-33-201U Neonatal Heated Wire Breathing System & Autofill Humidification Chamber are considered to be substantially equivalent to the Fisher & Paykel RT235 Breathing Circuit & MR290 Humidification Chamber. The comparison of features performance, materials and intended use (illustrated within tables included in this summary document), and evaluation of devices including safety, performance, function, compatibility, biological safety, electrical safety, electromagnetic compatibility (EMC) in accordance with relevant FDA recognized standards demonstrates that Flexicare's 038-33-201U Neonatal Heated Wire Breathing System is as safe and effective as the predicate device for its intended purpose.