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510(k) Summary K133516

APR 30 2014

Trade name	CO2 monitoring line & CO2 monitoring line with filter
C.F.R Section:	21 CFR 868.1400.
Device type:	Analyzer, Gas, Carbon-Dioxide, Gaseous-Phase
Product Code:	CCK
Manufacturer:	Flexicare Medical Limited Cynon Valley Business Park Mountain Ash, Mid. Glam. CF45 4ER. United Kingdom
Regulatory Affairs Contact:	Christopher Watkins Quality Regulatory & Technical Director Flexicare Medical Limited Cynon Valley Business Park Mountain Ash, Mid. Glam. CF45 4ER. United Kingdom
Telephone:	00 44 1443 471 593
Date Summary Prepared:	22nd April 2014
Common Name:	CO2 monitoring line
Classification:	Class 2
Predicate Device	Intersurgical - CO2 Monitoring line and CO2 monitoring line with filter, which was cleared for marketing by 510(k) No **K122075**

Description:

Flexicare's CO2 monitoring line is single patient use, small diameter tubing intended to be connected to a luer lock connector on a patient interface to allow for gas sampling from a patients exhaled breath by gas sampling equipment.
The Gas monitoring/analysing device will feature a pump, which draws expired breath from the patient through the monitoring line and into the gas analyser.
Flexicare's CO2 monitoring line is available with or without a 0.45µm hydrophobic filter, which prevents the transfer of water vapour down the monitoring line and into the gas sampling equipment.

Flexicare's CO2 monitoring lines feature clear construction to aid visual inspection of the device.

The CO2 monitoring line is a single patient use device, designed for use with one patient over a single course of treatment. The CO2 monitoring line is supplied in a sealed poly bag in a non sterile state and is not to be sterilized.

The Flexicare CO2 monitoring lines feature 2M & 3M length tubes.

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Part Numbers:

Part Number	Product description
010-700U	CO2 MONITORING LINE WITH MALE/MALE CONNECTORS - 2M
010-705U	CO2 MONITORING LINE WITH FEMALE/FEMALE CONNECTORS - 2M
010-710U	CO2 MONITORING LINE WITH MALE/FEMALE CONNECTORS - 2M
010-700XU	CO2 MONITORING LINE WITH MALE/MALE CONNECTORS - 3M
010-700AU	CO2 MONITORING LINE WITH MALE/MALE CONNECTORS - 2M – WITH FILTER
010-705AU	CO2 MONITORING LINE WITH FEMALE/FEMALE CONNECTORS - 2M – WITH FILTER
010-710AU	CO2 MONITORING LINE WITH MALE/FEMALE CONNECTORS - 2M – WITH FILTER
010-700XAU	CO2 MONITORING LINE WITH MALE/MALE CONNECTORS - 3M – WITH FILTER

Sizing

Part Number	Length (mm)	Tube OD (mm)	Tube ID (mm)
010-700U	2000	2.7	1.2
010-705U	2000	2.7	1.2
010-710U	2000	2.7	1.2
010-700XU	3000	2.7	1.2
010-700AU	2000	2.7	1.2
010-705AU	2000	2.7	1.2
010-710AU	2000	2.7	1.2
010-700XAU	3000	2.7	1.2

Intended Use:

CO2 Monitoring lines are intended to connect from a patient interface CO2 sampling port to the expired gas monitor.

Substantial Equivalence

Flexicare's CO2 monitoring line & CO2 monitoring line with filter have the same intended use as predicate device:

Intersurgical - CO2 Monitoring line and CO2 monitoring line with filter, which was cleared for marketing by 510(k) No **K122075**

Both Flexicare's CO2 monitoring lines and Intersurgical CO2 monitoring lines are single patient use devices.

Neither Flexicare's CO2 monitoring lines or Intersurgical CO2 monitoring lines are life supporting or life sustaining.

Neither Flexicare's CO2 monitoring lines or Intersurgical CO2 monitoring lines use software, and are not electronically driven.

Both Flexicare's CO2 monitoring lines and Intersurgical CO2 monitoring lines are supplied non- sterile in individual poly bags.

Both Flexicare's CO2 monitoring lines and Intersurgical CO2 monitoring lines are designed for the same intended use in the same intended conditions.

Both Flexicare's CO2 monitoring lines and Intersurgical CO2 monitoring lines consist of 3-4 components made from injection molded & extruded plastics.

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Both Flexicare's CO2 monitoring lines and Intersurgical CO2 monitoring lines are supplied either with or without 0.45µm hydrophobic filters. Flexicare's hydrophobic filter appeared to be identical to the Intersurgical filters in appearance and product marking. It is likely they are sourced from the same supplier.

From the performance testing it was discovered both Flexicare's and the predicate device tubes are manufactured from flexible PVC, and that both devices feature male and female luers with the option of a hydrophobic filter.

The technological characteristics of Flexicare's CO2 monitoring line and Intersurgical's CO2 monitoring line are very similar. These similarities are evident in the comparison table below.

	Flexicare - CO2 monitoring line K133516	**Intersurgical - CO2 Monitoring Line K122075**
Intended use		
Target Population	Any patient from which gas monitoring is required	Any patient from which gas monitoring is required
Indications for use	CO2 Monitoring lines are intended to connect from a patient interface CO2 sampling port to the expired gas monitor.	The CO2 monitoring lines are intended to connect from a CO2 sampling port to the expired gas monitor
Place of use	Hospitals	Hospitals
Product labeling	CO2 monitoring line	CO2 monitoring line
Single use or re-usable?	Single use	Single use
Design and performance		
Resistance to flow	8.8 mbar at 100ml/min flow 30.2 mbar at 300ml/min flow	15.2 mbar at 100ml/min flow 51.2 mbar at 300ml/min flow
Leakage	<1.0ml/min	<1.0ml/min
Connectors	2x luer lock connectors – male or female	2x luer lock connectors– male or female
Outer diameter	2.7mm	3.05mm
Inner diameter	1.2mm	1.47mm
Lengths available	2.0m, 3.0m	0.7m, 1.8m, 2.45m, 3.0m
Standards	ISO 594-2 (BS EN 1707:1997) , ISO 10993-3&5	ISO 594-2 (BS EN 1707:1997) , ISO 10993-3&5
Processes	Extrusion, injection moulding, adhesive bonding	Extrusion, injection moulding, adhesive bonding
Colours	None - colourless	None - colourless
Energy Used/delivered:	Gas is pulled away from the patient by a pump in the gas sampling device	Gas is pulled from one end of the tube to the other by a pump in the gas sampling device
Compatability :	Designed for use with gas monitoring device (for example a Capnograph) with luer connections to gas sampling tubing	Designed for use with gas monitoring device (for example a Capnograph) with luer connections to gas sampling tubing
Materials :	PVC (main line) and ABS (luer connectors)	PVC (main line) and Polycarbonate (luer connectors)

Biocompatibility:	Compliant with ISO 10993-3&5	Compliant with 10993-3&5
Sterility:	Non sterile	Non sterile
Storage	Store in a cool, dry place out of direct sunlight	Store in a cool, dry place out of direct sunlight
Component interactions	Tube – intact skin contact Connector – intact skin contact (whilst connecting to analyzing machine	Tube – intact skin contact Connector – intact skin contact (whilst connecting to analyzing machine
Intended use		
Target Population	Any patient from which gas monitoring is required	Any patient from which gas monitoring is required
Indications for use	CO2 Monitoring lines are intended to connect from a patient interface CO2 sampling port to the expired gas monitor.	The CO2 monitoring lines are intended to connect from a CO2 sampling port to the expired gas monitor
Place of use	Hospitals	Hospitals
Product labeling	CO2 monitoring line + Hydrophobic filter	CO2 monitoring line + Hydrophobic filter
Single use or re-usable?	Single use	Single use
Design and performance		
Resistance to flow	30.0 mbar at 100ml/min flow 95.7 mbar at 300ml/min flow	33.4 mbar at 100ml/min flow 114.5 mbar at 300ml/min flow
Leakage	<1.0ml/min	<1.0ml/min
Connectors	2 x luer lock connectors – male or female (plus luer lock male to luer lock female connection between monitoring line and filter)	2 x luer lock connectors – male or female (plus luer lock male to luer lock female connection between monitoring line and filter)
Outer diameter	2.7mm	3.05mm
Inner diameter	1.2mm	1.47mm
Length	2.0m, 3.0m	0.7m, 1.8m, 2.45m, 3.0m
Standards	ISO 594-2 (BS EN 1707:1997), ISO 10993-3&5	ISO 594-2 (BS EN 1707:1997), ISO 10993-3&5
Processes	Extrusion, injection moulding, adhesive bonding	Extrusion, injection moulding, adhesive bonding
Colours	None - colourless	None - colourless
Energy Used/delivered:	Gas is pulled away from the patient by a pump in the gas sampling device	Gas is pulled from one end of the tube to the other by a pump in the gas sampling device
Compatability :	Designed for use with gas monitoring device (for example a Capnograph) with luer connections to gas sampling tubing	Designed for use with gas monitoring device (for example a Capnograph) with luer connections to gas sampling tubing
Materials :	PVC (main line) and ABS (luer connectors)	PVC (main line) and Polycarbonate (luer connectors)
Biocompatibility:	Compliant with ISO 10993-3&5	Compliant with ISO 10993-3&5
Sterility:	Non sterile	Non sterile
Storage	Store in a cool, dry place out of direct sunlight	Store in a cool, dry place out of direct sunlight
Component interactions	Tube – intact skin contact Connector – intact skin contact (whilst connecting to analyzing machine	Tube – intact skin contact Connector – intact skin contact (whilst connecting to analyzing machine

	Filter - intact skin contact (whilst connecting to analyzing machine	Filter - intact skin contact (whilst connecting to analyzing machine

From the table above it is evident that the CO2 monitoring line devices from both manufacturers have very similar technological characteristics. Both devices feature the same number of components, have been made using the same manufacturing methods, have been manufactured from the same (or very similar) materials and critical dimensions (tube ID, Luer dimensions) are identical.
Any differences between the Flexicare and Intersurgical devices are stated below with justifications.

Differences

Both devices are simple products, comprising of 3 components each (4 each if with filter). There are very little differences between the two devices. Below are the only differences discovered.

The luer connectors of the Intersurgical predicate device are Polycarbonate, while Flexicare's luers are ABS. This difference in material is not crucial as both materials are amorphous polymers and have similar properties including high clarity, hardness, high impact strength and very low mould shrinkage.

The only other difference between the devices is that the Intersurgical sample has a frosted finish tube, which is purely a surface finish difference.

Non Clinical Tests Performed:

Test	Standard / Pre-determined Acceptance Criteria	Outcome
Visual inspection	Pre-determined Acceptance Criteria	All samples pass
Resistance to flow	Pre-determined Acceptance Criteria	All samples pass
Dimensional inspection. Length, ID, OD	Pre-determined Acceptance Criteria	All samples pass
Leakage	Pre-determined Acceptance Criteria	All samples pass
Performance – CO2 monitoring	Pre-determined Acceptance Criteria	All samples pass
Tensile testing	Pre-determined Acceptance Criteria	All samples pass
Luer connectors – Dimensional, leakage, connection, stress cracking	ISO 594-1 / BS EN 20594-1:1994 ISO 594-2 (superseded by BS EN 1707:1997)	All samples pass
Accelerated age testing	ASTM F1980	All samples pass
Cytotoxicity, Irritation, sensitization	BS EN ISO 10993-10:2010	All samples pass
	BS EN ISO 10993-5:2009	All samples pass
Genotoxicity	BS EN ISO 10993-3:2009	All samples pass

All the tests that were carried out on Flexicare's CO2 monitoring line are listed in the table above.

The tests selected to be carried out in order to determine substantial equivalence would test the critical aspects of the each device's functionality.

The visual & dimensional inspections were carried out to ensure that the Flexicare device had the same number of components, the same general assembly, the same material type and was dimensionally the same as (or very similar to) the predicate device. Both manufacturers' devices were found to be very similar in appearance, assembly, materials and dimensions with critical dimensions such as tube ID being identical.

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Resistance to flow testing was carried out to compare the level of resistance between Flexicare's CO2 monitoring line with Intersurgical's at the same flow rates. This aspect is critical as a higher resistance would restrict CO2 reaching the gas analyzer. Testing was carried out at 100ml/min and again at 300ml/min.

CO2 monitoring testing was carried out in order to assess whether the devices would detect CO2 from beneath the nostrils as this is the main purpose of the device. Samples were not assessed for % of CO2 detected as this depends on the patient-end device that the CO2 monitoring line is attached to. Both manufacturers' devices detected CO2 consistently, proving substantial equivalence.

Leak and tensile testing were also carried out as a leak or disconnection from sampling line to luer could result in less or no CO2 being drawn to the gas sampling device. Both Flexicare's and Intersurgical's devices passed the leak testing and withstood the pre-determined acceptance criteria of 40N tensile force without disconnection. This also proves substantial equivalence of the devices.

Conclusion

Flexicare's & Intersurgical's CO2 monitoring line & CO2 monitoring line with filter passed the performance testing when tested against methods and criteria from both pre-determined acceptance criteria test methods and relevant standards. The results of this testing show that the CO2 monitoring line & CO2 monitoring line with filter passes all performance tests that are critical to its substantially equivalent operation. In all tests the Flexicare device performed as well as or better than the Predicate device.
Flexicare's CO2 monitoring line & CO2 monitoring line with filter is substantially equivalent to, and performs as well as the marketed predicate device manufactured by Intersurgical.

Signature of contact Person:

Chris Watkins
Quality Regulatory & Technical Director

Dated: 22-04-2014

----------End of 510k Summary----------

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

April 30, 2014

Flexicare Medical Limited
Christopher Watkins
Quality Regulatory and Technical Director
Cynon Valley Business Park
Mountain Ash, Mid. Glamorgan
CF45 4ER, United Kingdom

Re: K133516
Trade Name: CO2 Monitoring Line & CO2 Monitoring Line with Filter
Regulation Number: 21 CFR 868.1400
Regulation Name: Carbon Dioxide Gas Analyzer
Regulatory Class: Class II
Product Code: CCK
Dated: March 26, 2014
Received: March 31, 2014

Dear Mr. Watkins:

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin Keith, M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known): K133516

Device Name: CO2 monitoring line & CO2 monitoring line with filter

Indications for Use:

CO2 Monitoring lines are intended to connect from a patient interface CO2 sampling port to the expired gas monitor.

Prescription Use ✔ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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