K122075

Section 5 510(k) Summary of Safety and Effectiveness

DEC 2 0 2012

Name: INTERSURGICAL INCORPORATED
Address: 417 Electronics Parkway
Liverpool, NY 13088
Date: December 19, 2012
Contact Person: Michael Zalewski – Assistant VP - RA/CS
Phone Number: 315-451-2900
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Trade Name: C02 Monitoring Line and C02 Monitoring Line with Filter

Common Name: C02 Monitoring Line and C02 Monitoring Line with Filter

Classification: 21 CFR 868.1400, Classification Name: Analyzer, Gas, Carbon Dioxide, Gaseous Phase – Accessory - Classification Product Code: CCK

Predicate Device:
Catheter Research Inc., Disposable Gas Sampling Lines, K946044. The CRI monitoring lines are designed for connection between a gas monitoring device and a patient interface device in which gas monitoring is required. CRI gas sampling lines are available with or without a hydrophobic filter for the prevention of water transfer along the sampling line and into the gas sampling equipment.

Description:

C02 Monitoring Line and Monitoring Line with Filter

The monitoring line tubing is single use, small diameter tubing intended to be connected to a port on a face mask or breathing circuit to allow for gas sampling from a patient's breath by gas sampling equipment. When used with a face mask the line connects between the female luer lock connector on the mask and a capnograph or similar gas monitoring device. The gas monitoring device will have a pump which pulls air from inside mask, along the monitoring line and into the gas monitoring equipment. The monitoring line is available with or without a hydrophobic filter, which prevents the transfer of water down the monitoring line and into the gas sampling equipment.

Indications for Use:
The C02 monitoring lines are intended to connect from a C02 sampling port to the expired gas monitor.

Section 5 510(k) Summary of Safety and Effectiveness (cont.)

Technological Characteristics Summary:
The intended use of the Intersurgical C02 Monitoring Line and Monitoring Line with Filter is comparable to the referenced predicate devices. The comparison of the data shows similar values for the key performance characteristics. Proposed devices show similar values for resistance to flow, leakage, connectors, outer diameter, inner diameter and static water load.

Characteristic Compared	C02 Monitoring Line	C02 Monitoring Line
		K946044
Intended Use:		
Target population	Any patient from which gas monitoring is required	Any patient from which gas monitoring is required
Indications for use	The C02 monitoring lines are intended to connect from a C02 sampling port to the expired gas monitor.	The gas sampling lines are intended to connect from a port in the face mask breathing circuit to the expired gas monitor.
Where used	Hospitals	Hospitals
Product Labelling	CO2 Monitoring Line	Gas Sampling Line
Single Use or Reusable?	Single Use	Single Use
Design and Performance:		
Resistance to Flow	8.1mbar at 100ml/min flow 20.7ml/min at 300ml/min flow	12.5mbar at 100ml/min flow 35.9ml/min at 300ml/min flow
Leakage	<1.0ml/min	<1.0ml/min
Connectors	2 x Luer Lock connectors	2 x Luer Lock connectors
Outer Diameter	3.05mm	2.95mm
Inner Diameter	1.47mm	1.34mm
Energy Used/Delivered:	Gas is pulled from one end of the tube to the other 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
Compatibility:	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 PC (luer connectors)	PVC (main line) and ABS (luer connectors)
Biocompatibility:	Compliant with ISO 10993	Compliant with ISO 10993
Sterility:	Non sterile	Non sterile

Section 5 510(k) Summary of Safety and Effectiveness (cont.)

Characteristic	CO2 Monitoring Lines + filter	CO2 Monitoring Line + Filter
		K946044
Intended Use:		
Target population	Any patient from which gas monitoring is required during the patient's breathing cycle	Any patient from which gas monitoring is required during the patient's breathing cycle
Indications for use	The C02 monitoring lines are intended to connect from a C02 sampling port to the expired gas monitor.	The gas sampling lines are intended to connect from a port in the face mask breathing circuit to the expired gas monitor.
Where used	Hospitals	Hospitals
Product Labelling	**CO2 Monitoring Line 2.45m + hydrophobic filter**	**Gas Sampling Line + filter**
Single Use or Reusable?	**Single Use**	**Single Use**
Design and Performance:		
Resistance to Flow	26.3mbar at 100ml/min flow 82.0mbar at 300ml/min flow	14.6mbar at 100ml/min flow 47.3mbar at 300ml/min flow
Leakage	<1.0ml/min	<1.0ml/min
Connectors	2 x Luer Lock connectors (plus luer lock Male to Luer lock Female connection between monitoring line and filter)	2 x Luer Lock connectors (plus luer lock Male to Luer lock Female connection between monitoring line and filter)
Outer Diameter	3.05mm	2.95mm
Inner Diameter	1.47mm	1.34mm
Static water load	Does not allow passage of water past filter media	Does not allow passage of water past filter media
Energy Used/Delivered:	Gas is pulled from one end of the tube to the other 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
Compatibility:	Designed for use with gas monitoring device (for example a capnograph) with luer connections for gas sampling tubing	Designed for use with gas monitoring device (for example a capnograph) with luer connections for gas sampling tubing
Materials:	PVC (main line), ABS (luer connectors and filter housing) and Nylon (filter media)	PVC (main line) and ABS (luer connectors)
Biocompatibility:	Compliant with ISO 10993	Compliant with ISO 10993
Sterility:	Non sterile	Non sterile

Section 5 510(k) Summary of Safety and Effectiveness (cont.)

Summary of Testing:
Nonclinical tests submitted to demonstrate substantial equivalence for the Monitoring Lines and Monitoring Lines with Filter include resistance to flow, leakage, connectors, outer diameter, inner diameter and static water load. All materials used in the C02 Monitoring Lines and Monitoring Lines with Filter have been evaluated according to tests outlined in ISO 10993-1 and meet the requirements of Bluebook Memo, General Program Memorandum G95-1 biocompatibility testing for cytotoxicity, sensitization, and irritation. The monitoring line and hydrophobic filter conform to clauses 4.2 to 4.7 of ISO 594-2:1998, which are considered the 'functional' aspects of the luer lock design, ranging from separation and assembly forces to durability.

Substantial Equivalence:
Intersurgical Incorporated has demonstrated that the proposed devices are safe and effective. They are considered to be substantially equivalent to the currently marketed predicate devices which have been previously reviewed for market clearance by the FDA.

K122075
Premarket Notification [510(k)] Number

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

December 20, 2012

Mr. Michael Zalewski
Vice President-RA/QA/CS
Intersurgical, Incorporated
417 Electronics Parkway
LIVERPOOL NY 13077

Re: K122075
Trade/Device Name: Line and C02 Monitoring Line with Filter
Regulation Number: 21 CFR 868.1400
Regulation Name: Carbon Dioxide Gas Analyzer
Regulatory Class: II
Product Code: CCK
Dated: December 4, 2012
Received: December 11, 2012

Dear Mr. Zalewski:

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.

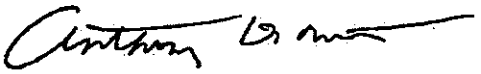
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4 Indications for Use Statement

510(k) Number (if known): K122075

Device Name:
C02 Monitoring Line and C02 Monitoring Line with Filter

Indications For Use:

The C02 monitoring lines are intended to connect from a C02 sampling port to the expired gas monitor.

Prescription Use XXX (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)

Lester W. Schultheis Jr
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(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K122075