K121927

510(k) Summary of Safety and Effectiveness Information

NOV 2 9 2012

DATE THIS SUMMARY WAS PREPARED

Nov 15, 2012

SUBMITTER NAME AND ESTABLISHMENT ADDRESS:

Oridion Medical 1987 Ltd.
7 HaMarpe Street, Har Hotzvim Science Based Industrial Park,
POB 45025, 91450 Jerusalem, Israel

ESTABLISHMENT REGISTRATION NUMBER

8044004

CONTACT PERSON:

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DEVICE INFORMATION

Proprietary Name: Carinal VitaLine™ Set
Common Name: Intubated Infant Neonatal CO2 sampling line
Product Classification: 73CCK Class II
This device is a capnograph accessory. It is classified as follows:
21 CFR 868.1400, carbon dioxide analyzer.

This device is classified identically to the cleared predicate device K980327.

PREDICATE DEVICE

Microstream FilterLine ICU, K980327 manufactured by Oridion Medical 1987 Ltd.

DEVICE DESCRIPTION

The Carinal VitaLine Set comprises Microstream FilterLine ICU that is modified to enable the clinician to select between central monitoring from the trachea above the carina via the monitoring lumen of the ETT and traditional monitoring with a CO2 sampling airway adapter. The following components are included in the Carinal VitaLine Set:

- sampling line
- airway adapter with tube and luer connected.

The Carinal VitaLine Set is designed for use with an infant neonatal size uncuffed endotracheal tube equipped with a monitoring lumen. The endotracheal tube must be supplied by the end user and is not provided by Oridion as part of the Carinal VitaLine.

The tubing leading to the CO2 monitor includes two dryer sections to support use in high humidity environments and prevent rapid occlusion of the tubing.

INTENDED USE/ INDICATION FOR USE

The Carinal VitaLine™ Set sampling line is intended to provide for CO2 measurement of intubated neonates and infants with a Microstream monitor. It enables either standard sampling via the airway adapter and main lumen of an endotracheal tube or sampling from the carina via the monitoring lumen of the same tube.

The set is intended for single patient use only.

BRIEF COMPARISON TO THE PREDICATE DEVICE

Feature	**Oridion** **MICROSTREAM FILTERLINE ICU – K980327**	**Oridion Carinal VitaLine Set**
Intended Use	The intended use of the Microstream FilterLine ICU sample line is conduct a sample of the patient's breathing from a ventilator or anesthesia machine airway to the gas measurement device for measuring the percentage of CO2 in the patient's exhalation	The Carinal VitaLine™ Set sampling line set is intended to provide for CO2 measurement of intubated neonates and infants with a Microstream monitor. It enables either standard sampling via the airway adapter and main lumen of an endotracheal tube or sampling from the carina via the monitoring lumen of the same tube.
Mode of operation	Used as a Microstream monitor accessory	Same
Intended population	All Intubated Patients (adult, pediatric, infant, neonates)	Intubated infant and neonatal patients
Patient Interface	Enables CO2 sampling from the ventilator tubing through an Airway Adapter which connects	Same Additionally, enables CO2 sampling above the carina via the monitoring

	from one side to the endotracheal tube (not supplied by the company) and from the other side to the ventilator.	lumen of an endotracheal tube (not supplied by the company). User can switch between interfaces.
Rise time	215mSec	240- 280mSec
Pressure Drop	35 mbar Max @ 50ml/min	33±6mBar at 50 mL/min.
Delay Time	2.7Sec typical @ 50ml/min	2.8Sec @ 50mL/min
Tensile Strength	≥2kg @30 cm/min	≥2kg @30 cm/min

SUMMARY OF TESTING

In order to demonstrate substantial equivalency to the predicate device the following bench tests were performed: Tensile Strength, Leak Tightness, Pressure Drop, Rise Time, and Delay Time.

SUBSTANTIAL EQUIVALENCE

The Carinal VitaLine Set is as safe and effective as the Microstream FilterLine ICU, K980327. It has similar intended use, similar indication for use and similar technological characteristics and principle of operation as its predicate device.

The minor differences between the Carinal VitaLine Set and its predicate device raise no issue of safety and effectiveness. Bench performance data demonstrate that the Carinal VitaLine Set is as safe and effective as the Microstream FilterLine ICU. Thus the Carinal VitaLine Set is substantially equivalent to its predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Ms. Dalia Givony
Director of Regulatory Affairs
Oridion Medical 1987 Limited
Har Hotzvim Science Park
POB 45025
Jerusalem, Israel 91450

NOV 2 9 2012

Re: K121927
Trade/Device Name: Carinal VitaLine™ Set
Regulation Number: 21 CFR 868.1400
Regulation Name: Carbon Dioxide Gas Analyzer
Regulatory Class: II
Product Code: CCK
Dated: November 15, 2012
Received: November 16, 2012

Dear Ms. Givony:

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,

Kwame O. Ulmer for

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

1. Statement of Indications for Use

(This document is not confidential)

Nov 15, 2012

Device Name:
Carinal VitaLine™ Set

Indications For Use:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use __X__ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

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

510(k) Number: K121927