

K980324



Oridion

APR 16 1998

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5. SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION IN THIS SUBMISSION

5.1. PRODUCT NAME

PROPRIETARY: Microstream Filterline OR/EMS

COMMON: Gas Sampling Line For Capnograph

5.2. ESTABLISHMENT REGISTRATION NUMBER

Establishment Registration Number: 8044004

5.3. ESTABLISHMENT ADDRESS:

Oridion Medical Ltd.

Har Hotzvim Science Based Industrial Park

POB 45025

91450 Jerusalem, Israel

5.4. DEVICE LISTING FDA FORM 2892:

A 733250

5.5. PRODUCT CLASSIFICATION

The Microstream Filterline OR/EMS sample line has not been classified. It was included as an accessory in FDA submission K964239. We believe that it falls under 21CFR868 anesthesiology devices.

5.6. INTENDED USE:

The intended use of the Microstream Filterline OR/EMS sample line is to 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.

5.7. DEVICE DESCRIPTION

The common product name for our accessory is a gas sampling tube. The gas sampling tube is used with a capnograph (carbon dioxide analyzer 21CFR 868.1400). There is a male Luer lock at one end of the device for connecting to the airway adapter in the ventilator or anesthesia machine airway and a female Luer lock on the other end for connecting to the capnograph. The two connectors are joined by a plastic tube and an in line hydrophobic filter.



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One end of the tube is connected to the source of the patient's breathing (exhalation) and the other end of the tube is connected to a capnograph. The capnograph has a pump that creates a vacuum of approximately 30mbar which draws a sample of the patient's breathing (exhalation) through the sampling tube into the capnograph for analysis of the CO₂ content of the patient's exhalation.

The most common way (for intubated patients) to connect the sampling tube to a point where it can get a sample of the patients breathing is to connect one end of the sample tube to a point on the ventilator or anesthesia machine airway circuit.

The anesthesiologist sometimes places a hydrophobic filter between the sample line and the capnograph to keep moisture from entering the capnograph. The Microstream Filterline OR/EM has integrated an in line hydrophobic filter between the patient and the Capnograph to reduce the amount of patient generated moisture that can enter the capnograph.

5. 8. SUBSTANTIAL EQUIVALENCE

The Microstream OR/EMS Filterline is identical to the same device described as an accessory to the NPB-75/Microcap Capnograph/pulse oximeter in approved submittal K964239.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 16 1998

Mr. Sanford Brown
Oridion Medical Ltd.
P.O. Box 45025
Jerusalem 91450
Israel

Re: K980324
Microstream Filterline OR/EMS
Regulatory Class: II (two)
Product Code: 73 CCK
Dated: January 26, 1998
Received: January 28, 1998

Dear Mr. Brown:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

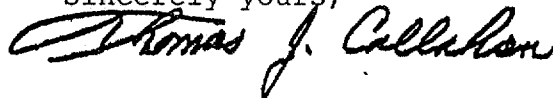
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure



Oridion

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JANUARY 26, 1998

3. INDICATIONS FOR USE

510(K) NUMBER (IF KNOWN): K980324

DEVICE NAME: MICROSTREAM FILTERLINE OR/EMS _____

INDICATIONS FOR USE:

THE MICROSTREAM FILTERLINE OR/EMS DEVICE IS USED WHENEVER THE PHYSICIAN NEEDS TO MEASURE THE CO₂ IN AN INTUBATED PATIENT'S BREATHING.

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

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

PRESCRIPTION USE OR OVER-THE-COUNTER USE
(PER 21 CFR 801.109)

(OPTIONAL FORMAT 1-2-96) 4/15/98

M. P...
(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K980324