Oridion Medical 1987 Ltd.
Dalia Givony
Regulatory and Clinical Affairs Manager
7 Hamarpe Street P.O. Box 45025
Jerusalem, 9777407 Il

Re: K181467
Trade/Device Name: Microstream Luer Adult-Pediatric Intubated Sampling Line, Microstream Advance Adult-Pediatric Intubated Filter Line
Regulation Number: 21 CFR 868.1400
Regulation Name: Carbon Dioxide Gas Analyzer
Regulatory Class: Class II
Product Code: CCK
Dated: December 30, 2018
Received: January 2, 2019

Dear Dalia 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Todd D. Courtney -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

**001_Indications for Use Statement**

*K181467*

**Device Name:**
Microstream™ Luer Adult-Pediatric Intubated Sampling Line
Microstream™ Advance Adult-Pediatric Intubated Filter Line

**Indications for Use:**

Intended to conduct a sample of the patient's breathing from a ventilator or anesthesia machine to a gas measurement device for measuring the percentage of CO2 in the patient's exhaled breath. The set is intended for single patient use only. Intended population: Intubated Adult- Pediatric patients.

**(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)

# 510K Summary

## DATE THIS SUMMARY WAS PREPARED

Feb 07, 2019

## SUBMITTER NAME AND ESTABLISHMENT ADDRESS:

Oridion Medical 1987 Ltd.
7 HaMarpe Street, P.O. Box 45025,
Jerusalem 9777407, Israel

## ESTABLISHMENT REGISTRATION NUMBER

8044004

## CONTACT PERSON:

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## PRODUCTS TRADE NAME

Microstream™ Luer Adult-Pediatric Intubated Sampling Line
Microstream™ Advance Adult-Pediatric Intubated Filter Line

## COMMON:

Intubated CO2 Sampling Lines

## CLASSIFICATION:

Product Classification: CCK Class II

This device is a capnograph accessory. It is classified as follows:

21 CFR 868.1400, carbon dioxide gas analyzer.

This device is classified identically to the cleared predicate device K980324 and K980327 (reference device).

**PREDICATE DEVICE:**

Microstream FilterLine OR/EMS cleared under K980324

**REFERENCE DEVICE:**

Microstream FilterLine ICU cleared under K980327

**DEVICE DESCRIPTION:**

Similar to their predicates the devices are non-sterile, disposable, single patient use, intended to conduct a sample of the patient's breathing from a ventilator or anesthesia machine to a device for measuring the percentage of CO2 in the patient's exhalation when connected to a capnograph.

The device's main components are PVC tubing, airway adapter and a luer connector.

*Microstream™ Advance Adult-Pediatric Intubated Filter Line* can be used only with Microstream™ capnography technology.

*Microstream™ Luer Adult-Pediatric Intubated Sampling Line* can be used with any capnograph with a luer connection.

An Accessory (extension line) to the proposed devices: *Microstream™ Advance Filter Line, MRI is composed of* PVC tubing and a luer connector. It is Intended to be used when longer tubing is required to allow CO2 sampling for environments such as an MRI suite. The straight tubing is then connected to the FilterLine/ Sampling Line end from one side and from the other side to the monitor, which is placed outside of MRI suite.

The main reason for this submission is the modification of the CO2 tubing to material not made with phthalates.

**INDICATIONS FOR USE:**

Intended to conduct a sample of the patient's breathing from a ventilator or

anesthesia machine to a gas measurement device for measuring the percentage of CO2 in the patient's exhaled breath. The set is intended for single patient use only. Intended population: Intubated Adult- Pediatric patients.

**COMPARISON TO PREDICATE:**

| **Feature** | **Microstream™ FilterLine OR/EMS - K980324 (predicate)** | **Microstream™ FilterLine ICU- K980327 (reference predicate)** | **Microstream™ Luer Adult-Pediatric Intubated Sampling Line** | **Microstream™ Advance Adult-Pediatric Intubated Filter Line** | **Accessory: Microstream™ Advance Filter Line, MRI.** |
|---|---|---|---|---|---|
| Mode of operation | For use with Microstream Capnography technology | For use with Microstream Capnography technology | For use with any Capnograph with luer connection | Same as K980327 | Same as K980324 |
| Single patient use | Yes | Yes | Yes | Yes | Yes |
| Biocompatibility | ISO 10993-1 | ISO 10993-1 | ISO 10993-1 | ISO 10993-1 | ISO 10993-1 |
| Tubing Length | 2 m | 2 m | 2m | 2m/4m | 9m |
| Tubing material | Made with phthalates | Made with phthalates | Made without phthalates | Made without phthalates | Made without phthalates |
| Dehumidifier tubing | N/A | Nafion | N/A | Same as K980327 | N/A |
| Pressure Drop | Not specified | Not specified | ≤70mBar@180ml/min, sea level | ≤75[mbar] @ max 4m length; 50[mL/min], sea level | ≤75[mbar] @50[mL/min], sea level |
| Leak Tightness | 2 mBar/sec leak rate @ 100mBar under pressure | 2 mBar/sec leak rate @ 100mBar under pressure | Same as K980324 | Same as K980327 | Same as K980324 |
| Tensile Strength | Pull test of at least 2kg | Pull test of at least 2kg | Same as K980324 | Same as K980327 | Same as K980324 |

**CLINICAL/ NON-CLINICAL:**

The devices are composed from the following main patient contacting components: CO2 tubing (PVC), dehumidifier (Nafion) and air way connector (ABS). Biocompatibility testing, according to ISO 10993 and FDA guidance, which include cytotoxicity, sensitization and irritation as well as risk assessment, were conducted to assess the safe use of the proposed modified devices as externally communicating device with indirect contact with tissue, for prolonged use (>24 hours-30 days).

**PERFORMANCE DATA:**

Bench testing was conducted to ensure the devices' performance and to demonstrate similarity to the predicate devices. This bench testing includes mainly pressure drop, tensile strength, and leak tightness.

**CONCLUSION:**

The results show that the proposed devices are substantially equivalent to their predicates with no different questions of safety and effectiveness.