# Appendix D. 510(k) Summary of Safety and Effectiveness K121026

Name: INTERSURGICAL INCORPORATED
Address: 417 Electronics Parkway
Liverpool, NY 13088

NOV 2 2012

Date: October 11, 2012

Contact Person: Michael Zalewski – VP RA/QA/CS
Phone Number: 315-451-2900
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## Description of Device:

The breathing filer is classified as "Breathing Circuit Bacterial Filters" according to 21 CFR 868.5260. They are all in Regulatory Class II and have a product code of CAH.

Principle of operation:

The Flo-Guard breathing filter is designed to be placed at the machine end of a breathing system to protect the patient and machine against cross contamination while maintaining a low resistance across a wide range of flow rates. The gas flow path is simple, the pathway is through the 22F to the 22M connection on the inspiratory breath and should the filter be used on the expiratory side, from the 22M to the 22F on the expired breath.

The Flo-Guard is a single use product. The low resistance makes it an ideal filter for use in both the hospital and the home where high flow rates may potentially be used; this includes CPAP, BIPAP and cough assist applications. The filter has been designed to protect between the machine and breathing circuit interfaces.

## Predicate Devices:

The 1690030 - Intersurgical Flo - Guard Breathing Filter is substantially equivalent to the Respironics Breathing Filter. The Respironics Filter is made by King Systems.
The Respironics Bacteria Filter 342077 was chosen as a suitable predicate as the intended use and specification is similar to that of the Flo-Guard 1690030 filter. The 1690030 and the 342007 are both intended to be used as an accessory for CPAP and bi-level devices. Both devices are single use and both intended to be used as a bacterial filter.

The devices have comparable sizes, volumes and weights. The two devices have similar flow vs. pressure curves and the bacterial filtration efficiencies are similar. Both the 1690030 and 342077 have 22mm conical taper connections. See the technological characteristic summary for performance details.

## Indications for Use:

The Intersurgical Flo - Guard Breathing Filter is for use at machine end connections in home and hospital breathing system applications. It is designed to reduce bacterial/viral transmissions in order to protect the patient and respiratory equipment.

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## Indications for Use (continued):

The filter is single patient use for an adult target patient population, is intended for use within breathing systems in healthcare and home environments where ventilation is required and a maximum duration of 24 hours.

## Technological Characteristics Summary:

The intended use of the Intersurgical Flo - Guard Breathing Filter is comparable to the referenced predicate device. The comparison of the data shows similar values for the key performance characteristics. Proposed devices show similar values for filtration efficiency, dead space and resistance to flow when compared to the legally marketed devices.

| **Characteristic Compared**<br><br>**510 K** | **[510(k) DEVICE]**<br>**1690030** | **[PREDICATE DEVICE]**<br>**Respironics**<br>**K973797** |
|---|---|---|
| **Product Labeling** | 99.99% BFE & 99.95% VFE See Performance Testing Data. | 99.99% BFE & VFE |
| **Intended Use** | It is designed to reduce bacterial/viral transmissions between the patient and equipment. | It is designed to reduce bacterial/viral transmissions between the patient and equipment. |
| **Target Population** | All | All |
| **Environment of Use** | Clinical | Clinical |
| **Maximum Duration of Use** | 24 hours | |
| **Physical Characteristics** | Round/Cylindrical | Round/Cylindrical |
| **Approximate Volume(ml)** | 82 ml | 74 ml |
| **Resistance** | 0.4 cm H20 at 30 l/min | 0.7 cm H20 at 30 l/min |
| **Weight** | 28 g | 29 g |
| **Type of Filtration** | Electrostatic | Electrostatic |

Characteristics and performance criteria

The 1690030 is a Bacterial/viral filter capable of delivering low resistance values at high flows. It is designed to accompany BiPAP circuits and cough assist circuits for systems and is an expiratory silencer kit for neonatal ventilators also to be available as a stand alone low resistance product. The Respironics device is also a low resistance breathing system bacterial filter.

Test methods:

Leakage is tested by applying and maintaining an internal gas pressure by introducing air into the filter and recording the flow of air required maintaining that pressure.
Resistance to flow is tested by measuring the pressure increase at the rated flow through the filter
Filtration efficiency is tested at an external test house by use of the Henderson rig.
Compressible volume is by recording internal pressure over time and using a derivative of the gas law $P_1V_1 = P_2V_2$Weight was measure by use of a calibrated balance.The filter is intended for use for a maximum duration of 24 hours. This has been verified through conditioning testing. Filters were tested after 24 hours on a ventilator and after 24 hours on the moisture return rig.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

NOV 2 2012

Intersurgical, Incorporated
Mr. Michael Zalewski
Vice President – RA/QA/CS
417 Electronics Parkway
Liverpool, New York 13088

Re: K121026
Trade/Device Name: 1690030 Flo – Guard Breathing Filter
Regulation Number: 21 CFR 868.5260
Regulation Name: Breathing Circuit Bacterial Filter
Regulatory Class: II
Product Code: CAH
Dated: October 11, 2012
Received: October 16, 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,

for

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

Enclosure

## 10. INDICATIONS FOR USE

**510(k) Number (if known):**

**Device Name:**
1690030 Flo - Guard Breathing Filter

Indications For Use:

The Intersurgical Flo - Guard Breathing Filter is for use at machine end connections in home and hospital breathing system applications. It is designed to reduce bacterial/viral transmissions in order to protect the patient and respiratory equipment.

The filter is single patient use for an adult target patient population, is intended for use within breathing systems in healthcare and home environments where ventilation is required and a maximum duration of 24 hours.

Prescription Use XXX or Over-The-Counter Use _____
(Per 21 CFR 801.109)

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

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Concurrence of CDRH

L Schultes

**(Division Sign-Off)**
**Division of Anesthesiology, General Hospital Infection Control, Dental Devices**

**510(k) Number:** K121026