K122077

JAN 10 2013

Section 5 510(k) Summary of Safety and Effectiveness

Name: INTERSURGICAL INCORPORATED
Address: 417 Electronics Parkway
Liverpool, NY 13088
Date: January 10, 2013
Contact Person: Michael Zalewski – VP RA/QA/CS
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Classification: 21 CFR 868.2600, Classification Name: Monitor, Airway Pressure
Classification Product Code: 73 CAP

Predicate Devices:

The Ambu Disposable Pressure Manometer, REF 322004000 was chosen as a suitable predicate as the intended use and function is similar to that of the 7160030 In-line Manometer. The 7160030 and Ambu manometers are both intended for monitoring a patient's airway pressure. Both are intended for use in conjunction with a resuscitator and should only be used by personnel trained in resuscitation or airway management.

The devices have similar measurements limits and display increments. Both devices specify the pressure via a brightly colored indicator. In both devices the indicator moves in one axis along a transparent cylinder, the diameter of the indicator is similar to that of the cylinder. A balance of the force exerted by the air in the system and the force exerted by a calibrated spring defines the indicator position. The display on each manometer is a similar size and the pressure is specified where the indicator lines up with number marked on the outside of the transparent cylinder.

Description:
The Intersurgical 7160030 Manometer is an inline manometer for monitoring the pressure delivered to patients via resuscitation systems and Mapleson C breathing circuits.
The 7160030 manometer has an operating range of 0 – 60 mbar and a stated accuracy of +/- 10mbar. The pressure is read where the internal red indicator disk lines up with the pressure indication mark on the outside of the transparent manometer cylinder.

The 7160030 manometer specify the patient pressure via a brightly colored indicator. The indicator moves in one axis along a transparent cylinder. The diameter of the indicator is similar to that of the cylinder. A balance of the force exerted by the air in the system and the force exerted by a calibrated spring defines the indicator position. The display on each manometer is a similar size and the pressure is specified where the indicator lines up with number marked on the outside of the transparent cylinder.

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The Manometer connects to the resuscitator / Mapleson C system via a 3 way, 15mm Female/22mm Male – 22mm Female connector. The 3-way connector tapers are compliant with ISO 5356-1. The manometer can be rotated to the desired orientation for ease of use via a friction fit elastomeric elbow.

The 7160030 Manometer is single patient use. The manometer is to be used in hospital, ambulance, and/or environments where resuscitation is required. The manometer must only be used by personnel trained in resuscitation and/or airway management.

Indications for Use:

The Intersurgical In-line single patient use manometer is intended to be used for monitoring the patient's airway pressure during ventilation. The manometer is to be used with resuscitation systems and Mapleson C breathing circuits.

Technological Characteristics Summary:

The intended use of the Intersurgical Manometer 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 measurement limits, display increments, and accuracy when compared to the legally marketed devices.

Device Comparison Table

Characteristics	Intersurgical 7160030	Ambu 322004000 K 040991
Intended use	The Intersurgical In-line manometer is intended to be used for monitoring the patient's airway pressure.	The Ambu Disposable Pressure Manometer is intended to be used for monitoring the patient's airway pressure.
Indications for use	The Intersurgical In-line single patient use manometer is intended to be used for monitoring the patient's airway pressure during ventilation. The manometer is to be used with resuscitation systems and Mapleson C breathing circuits.	Single patient use.
Target population	All	All
Where used	Hospital, ambulance, and all other environments where patient resuscitation is required. Manometer must only be used by personnel trained in resuscitation and/or airway management.	Ambu Disposable Pressure Manometer must only be used by personnel trained in resuscitation and/or airway management.
Manometer size (Width x Length)	17mm x 63mm	22mm x 55mm
Weight	20.3g	6.7g

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Connections	22M/15F – 22F [ISO 5356-1]	Proprietary ID 3.7mm
Measurement limits	0 – 60cmH2O	0 – 60cmH2O
Display Increments	0, 10, 20, 30, 40, 50, 60 cmH2O	5, 10, 15, 20, 30, 40, 60 cmH2O
Stated accuracy of the reading:		
- at 10, 20 & 30 cmH2O		± 2 mbar
- at 10 cmH2O	± 2 mbar	
- at 20 cmH2O	± 4 mbar	
- at 30 cmH2O	± 5 mbar	
- at 40 cmH20	± 5 mbar	± 3 mbar
- at 50 cmH2O	± 7 mbar	
- at 60 cmH2O	± 7 mbar	± 5 mbar
Measured accuracy:		
- at 10, 20 & 30 cmH2O		± 2 mbar
- at 10 cmH2O	± 2 mbar	
- at 20 cmH2O	± 4 mbar	
- at 30 cmH2O	± 5 mbar	
- at 40 cmH20	± 5 mbar	± 4 mbar
- at 50 cmH2O	± 7 mbar	
- at 60 cmH2O	± 7 mbar	± 6 mbar
Standards met	ISO 5356-1	-
Materials	Polycarbonate, Stainless steel, Silicone, Latex free, PVC free	Polypropylene, Silicone, TPE, SAN, Steel, Latex free, PVC free
Phthalates	Phthalate free	Unknown
Biocompatibility	ISO 10993	Unknown
Sterility	No	No
Compatibility with the environment and other devices	To be used with Resuscitators and Mapleson C circuit	To be used with Ambu resuscitators or other resuscitators hyperinflation bags, CPAP masks or circuits, if specified by the manufacturer

Summary of Testing:

Nonclinical tests submitted to demonstrate substantial equivalence for the Manometers include Vertical and Horizontal Pressures, Weight and Size and Tapers when compared to the legally marketed device. All materials used in the Manometer 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 Manometer connectors meet the requirements of Anesthetic and respiratory equipment – conical connectors: Part 1: Cones and Sockets ISO 5356-1:2004.

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

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

January 10, 2013

Mr. Michael Zalewski
Vice President, RA/QA/CS
Intersurgical, Incorporated
417 Electronics Parkway
LIVERPOOL NY 13088

Re: K122077
Trade/Device Name: 7160030 Manometer
Regulation Number: 21 CFR 868.2600
Regulation Name: Airway Pressure Monitor
Regulatory Class: II
Product Code: CAP
Dated: December 18, 2012
Received: December 26, 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,

Kwame O. Ulmer

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): K122077

Device Name:
Product # 7160030 Manometer

Indications For Use:

The Intersurgical In-line single patient use manometer is intended to be used for monitoring the patient's airway pressure during ventilation. The manometer is to be used with resuscitation systems and Mapleson C breathing circuits.

Prescription Use _XXX_ AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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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

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