

K121747

MAR 14 2013

Section 5 - 510(k) Summary of Safety and Effectiveness

Name: INTERSURGICAL INCORPORATED
Address: 417 Electronics Parkway
Liverpool, NY 13088
Date: March 1, 2013, 2013
Contact Person: Michael Zalewski – VP RA/QA/CS
Phone Number: 315-451-2900
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Trade Name: FaceFit Ported NIV Masks

Common Name: Non-Invasive Ventilation Masks

Classification: 21 CFR 868.5905, 73 BZD (Class II) Accessory to Ventilator.

Predicate Device: Resmed Mirage Full Face Mask (K063011) for FaceFit Ported NIV Mask.

Description: The Intersurgical FaceFit Ported NIV Mask provides a seal such that air flow from a positive pressure source is directed to the patient's nose or mouth. The mask is held in place with adjustable headgear that straps the mask to the face. The Intersurgical Face Fit Mask is safe when used under the conditions and purposes intended as indicated in the labeling provided with the product.

FaceFit Ported Mask with a CO2 port for use with BIPAP and CPAP machines. The FaceFit Ported Mask features an anti-asphyxiation valve that will allow patients using a CPAP or BIPAP machine to breathe spontaneously through the mask in the event of a machine failure or system disconnection. The FaceFit ported mask is available in small, medium and large sizes.

Indications for Use:

Indications For Use: The FaceFit Ported Mask channels airflow noninvasively to a patient from a positive airway pressure device such as a continuous positive airway pressure (CPAP) or bi-level system.

This is a disposable mask. It is intended to be used for 24 hours of treatment of a single patient only, and then discarded. The masks are intended to be used in hospitals.

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Technological Characteristics Summary:

The intended use of the Intersurgical NIV masks is comparable to the referenced predicate devices. The comparison of the data shows similar values for the key performance characteristics. Proposed devices show similar values for CO2 Rebreathing (%), Patient Respiratory Resistance, and valve function when compared to the legally marketed devices. The masks connect to conventional air delivery hose between the mask and the positive airway-pressure source via standard conical connectors (ref: ISO 5356-1).

Characteristic Compared	[510(k) DEVICE] FACEFIT MASK WITH CO2 PORT	[PREDICATE DEVICE] RESMED MIRAGE FULL FACE MASK (K063011)
Target Patient Population	Adult patients for whom positive airway pressure treatment has been prescribed	Adult patients for whom positive airway pressure treatment has been prescribed
Environment of Use	Single patient re-use in the home environment and/or hospital/institutional environment.	Single patient re-use in the home environment and/or multi-patient reuse in the hospital/institutional environment.
Maximum Duration of Use	24 Hours	Unknown
Patient Use	Single Patient Use	Single /multi Patient Use
Material Composition	A polypropylene mask body, a silicone retained cap, a silicone seal around the mask, a nylon bridge, a silicone anti-asphyxiation valve, a laminated polyester strap and a Velcro adjustable head strap.	A Polycarbonate mask body, two silicone retained caps, a silicone seal around the mask, a silicone anti-asphyxiation valve, a laminated polyester strap and a Velcro adjustable head strap, a silicon forehead support cushion.
Specifications and Dimensions	See Engineering Drawings – Appendix I	See Dimensions of predicate NIV masks

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Characteristic Compared	[510(k) DEVICE] FACEFIT MASK WITH CO2 PORT	[PREDICATE DEVICE] RESMED MIRAGE FULL FACE MASK (K063011)
Mask Design Feature	<ul style="list-style-type: none"> • Anti-asphyxia valve • 22mm Male ventilator /patient interface • Vent holes to reduce CO2 rebreathing • Quick release strap clip • O2 supply connection/ pressure monitoring port 	<ul style="list-style-type: none"> • Anti-asphyxia valve • Swivel 22mm Male ventilator /patient interface • Vent holes to reduce CO2 rebreathing • Quick release strap clip • O2 supply connection/ pressure monitoring ports • Additional forehead support
Operational Principle	<p>The mask forms a seal around the patient's nose and mouth. An adjustable harness holds the mask securely in place. The mask connects to a CPAP ventilator that delivers positive airway pressure treatment. The mask has vent holes that allow expired CO2 to be flushed from the mask and reduce patient CO2 rebreathing. If the ventilator malfunctions the mask has an anti-asphyxiation valve that will allow the patient to continue to breath spontaneously. The harness has an easy to operate clip that allows the mask to be removed quickly. The mask has an auxiliary connection port through which supplementary O2 can be introduced, or the mask pressure can be monitored.</p>	<p>The mask forms a seal around the patient's nose and mouth. An adjustable harness holds the mask securely in place. The mask connects to a CPAP ventilator that delivers positive airway pressure treatment. The mask has vent holes that allow expired CO2 to be flushed from the mask and reduce patient CO2 rebreathing. If the ventilator malfunctions the mask has an anti-asphyxiation valve that will allow the patient to continue to breath spontaneously. The harness has an easy to operate clip that allows the mask to be removed quickly. The mask has two auxiliary connection ports through which supplementary O2 can be introduced, or the mask pressure can be monitored.</p>
Physical Characteristics:		
Volume ml.	123	174
CO2 Rebreathing (%)	0.79 (PCP Open)/0.96 (PCP Closed)	2.14 (PCP Open)/2.06 (PCP Closed)
Patient Respiratory Resistance mb. PCP Open	0.0 (Inhalation)/0.0 (Expiration) With a Peak Flow of 20 l/min	0.0 (Inhalation)/0.1 (Expiration) With a Peak Flow of 20 l/min
Patient Respiratory Resistance mb. PCP Closed	0.0 (Inhalation)/0.0 (Expiration) With a Peak Flow of 20 l/min	0.1 (Inhalation)/0.0 (Expiration) With a Peak Flow of 20 l/min
Valve Function Close	58 l/min flow at 1.5 mb pressure	59 l/min flow at 0.7 mb pressure
Valve Function Open	-0.1 mb pressure	16.8 l/min flow at 0.4 mb pressure

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Summary of Testing:

Nonclinical tests submitted to demonstrate substantial equivalence for the NIV masks include CO2 Rebreathing (%), Patient Respiratory Resistance, and valve function when compared to the legally marketed devices. All materials used in the NIV masks 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 mask connectors meet the requirements of Anesthetic and respiratory equipment – conical connectors: Part 1: Cones and Sockets ISO 5356-1:2004.

Substantial Equivalence:

Intersurgical Incorporated has demonstrated that the proposed devices are safe and effective. They are considered to be substantially equivalent to the currently marketed predicate devices which have been previously reviewed for market clearance by the FDA.

K121747

Premarket Notification [510(k)] Number



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

March 14, 2013

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

Re: K121747

Trade/Device Name: Product #2250030 – FaceFit NIV Mask with port Small
Product #2251030 – FaceFit NIV Mask with port Medium
Product #2252030 – FaceFit NIV Mask with port Large

Regulation Number: 21 CFR 868.5905

Regulation Name: Noncontinuous Ventilator (IPPB)

Regulatory Class: II

Product Code: BZD

Dated: March 1, 2013

Received: March 5, 2013

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" (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 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

Section 4 Indications for Use Statement

510(k) Number (if known): K121747

Device Name:

Product # 2250030 – FaceFit NIV Mask with port Small

Product # 2251030 – FaceFit NIV Mask with port Medium

Product # 2252030 – FaceFit NIV Mask with port Large

Indications For Use: The FaceFit Ported Mask channels airflow noninvasively to a patient from a positive airway pressure device such as a continuous positive airway pressure (CPAP) or bi-level system.

This is a disposable mask. It is intended to be used for 24 hours of treatment of a single patient only, and then discarded. The masks are intended to be used in hospitals.

Prescription Use XXX
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Lester W. Schultheis Jr
2013.03.13 15:38:42 -04'00'

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

510(k) Number: K121747