OCT 13 2011

Section 5: **510(k) SUMMARY**

[As required by 21 CFR §807.92(c)]

DATE PREPARED: March 28, 2011

Revised September 8, 2011

OFFICIAL CONTACT: Albert A. Lucio

Managing Partner

3B Products, LLC

1142 N. Scenic Highway

Lake Wales, FL 33853

Tel: (863) 676-5948

Email: alucio@3Bproducts.com

DEVICE TRADE NAME: 3B FLEX-LITE™

DEVICE COMMON NAME/

CLASSIFICATION NAME: Vented Nasal Mask:

Accessory to Noncontinuous Ventilator (IPPB)

CLASSIFICATION: 21 CFR 868.5905, 73 BZD (CLASS II)

PREDICATE DEVICES:

- Manufacturer: InnoMed Technologies, Inc.
  Trade Name: Nasal-Aire II
  510(k) Number: K022465

Manufacturer: Resmed, Ltd.

Trade Name: Swift FX

510(k) Number: K090244

DEVICE DESCRIPTION

The 3B Flex-Lite™ is a mask interface, of the nasal pillow variety, that directs airflow from a positive pressure device to the patient's nose. The mask is held in place with adjustable headgear that straps the mask to the face.

The 3B Flex-Lite™ is safe when used under the conditions and purposes intended as indicated in the labeling provided with the product.

The 3B Flex-Lite™ is a prescription device supplied non-sterile.

INTENDED USE

The 3B Flex-Lite™ channels airflow noninvasively to a patient from a positive airway pressure (PAP) device such as a continuous positive airway pressure (CPAP) or a bilevel system. The 3B Flex-Lite™ is:

(1) to be used by adult patients (>66lb / 30 kg);

(2) to be used for single-patient reuse in the home environment and multipatient reuse in the hospital/institutional environment.

(3) to be used in the following environments: home, hospital, and sub-acute institutions.

(4) intended for prescription use.

CONTRAINDICATIONS: None

TECHNOLOGICAL CHARACTERISTICS COMPARISON

The 3B Flex-Lite™ is differentiated from the predicate devices based primarily on differences in form, fit and comfort. The headgear is constructed out of Breath-O-Prene™ fabric, a laminated knit textile which serves as the loop for a Velcro fastener. Breath-O-Prene™ is a popular fabric for the CPAP headgear market used in the predicate devise Swift FX, and is also currently being used in similar applications by several other manufacturers, including Phillips Respironics GoLife Nasal Mask K110008) , Fisher & Paykel (Opus Nasal Mask K063036) and Resmed (Ultra Mirage Nasal Mask K050359).

The nasal mask itself incorporates four vent holes to provide continuous air leak to flush out and minimize the amount of CO2 rebreathed by the patient. The design of the mask components is such that the incorporation of these vent-holes does not interfere with the intended performance of the mask.

The 3B Flex-Lite™ nasal mask is very similar to the predicate InnoMed Nasal Aire-II mask. Both are cannula style mask systems with similar performance characteristics. Performance bench testing of both the 3B Flex-Lite™ and the Nasal Aire II were conducted. These tests demonstrate substantial equivalence of the proposed device with the predicate device. Copies of test reports are included in Appendix A.

The 3B Flex-Lite™ is similar to the predicate Resmed Swift FX inasmuch as they have similar air seal systems (i.e. nasal pillow design) and utilize the same headgear fabric (i.e. Breath-O-Prene™). A summary of the comparisons of the proposed device and the predicate devises is shown below in tabular form:

COMPARATIVE TABLE:

FEATURES	PREDICATE NASAL-AIRE II (K022465)	PREDICATE SWIFT FX (K090244)	PROPOSED DEVICE 3B FLEX-LITE (K103434)
Indications for Use	A patient interface accessory for use with CPAP and bi-level systems used in the treatment of adult OSA and/or ventilator support.	A patient interface accessory for use with CPAP and bi-level systems used in the treatment of adult OSA and/or ventilator support.	A patient interface accessory for use with CPAP and bi-level systems used in the treatment of adult OSA and/or ventilator support.
Environment of Use	Hospitals, sub-acute institutions, sleep laboratories and home.	Same	Same
Patient Population	Adult	Same	Same
Contraindications	None	None	None
Single patient, multi-use	Yes	Yes	Yes
Components	Nasal interface (no headgear)	Nasal interface with pillows and headgear	Nasal interface with pillows and headgear
Dead Space	Interface – 24-28 ml / Pillows 2-4 ml		Interface 10.5ml Pillows 3.5 ml
Fixed leak port	Yes	Yes	Yes

Deliverable pressure range	3-18 cmH20	4-20 cmH20	4-20 cmH20
Materials: **Nasal Interface** **Headgear**	 Silicone None	 Silicone Breath-O-Prene™	 Silicone (Biocompatibility per ISO 10993-1) Breath-O-Prene™
Comparative testing for safety and efficacy	Flow vs. Leak Pressure Dead space CO2 rebreathing	Flow vs. Leak Pressure Dead space CO2 rebreathing	Flow vs. Leak Pressure Dead space CO2 rebreathing

Non-clinical Tests

Testing of the 3B Flex-Lite™ was compared to the predicate InnoMed Nasal Aire II for performance and safety. Performance testing of both the proposed device, the 3B Flex-Lite™, and the Nasal-Aire II predicate device was performed by Piper Medical. A copy of the test report dated March 23, 2011 is annexed at Appendix A.

In terms of design, both the Nasal-Aire II and the proposed device are cannula style nasal interfaces, with the air flow supplied to the interface from lateral sides. The performance bench testing consisted of three sets of testing: passive exhalation port flow (App. A at p. 6), resistance to flow (App. A at p. 8), CO2 re-breathing percentage (App. at p. 9), and measurement of dead space (App. A at p. 9). Based on the results of these tests, the report finds that the 3B Flex-Lite™ is "substantially equivalent to the Nasal-Aire II in terms of performance".

Substantial Equivalence Conclusion:

3B Flex-Lite™ is substantially equivalent to the predicate devices. It has the same intended use. It has similar technological characteristics to both predicates. It does not raise new questions of safety and effectiveness. And, it is at least as safe and effective as the predicate devices Nasal-Aire II and Swift FX.

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

OCT 13 2011

Mr. Albert A. Lucio
Managing Partner
3B Products, LLC
1142 N. Scenic Highway
Lake Wales, Florida 33853

Re: K103434
Trade/Device Name: Flex-Lite™ CPAP Nasal Pillows Mask
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator
Regulatory Class: II
Product Code: BZD
Dated: September 15, 2011
Received: September 20, 2011

Dear Mr. Lucio:

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

4.0 Indications for Use Form

510(k) Number (if known): **K103434**

Device Name: Flex-Lite™ CPAP Nasal Pillows Mask

Indications for Use:

1. To be used by adult patients (>66lb /30kg);
2. To be used for single-patient reuse in the home environment or multi-patient reuse in the hospital/institutional environment;
3. To be used in the following environments: Home, Hospital, and sub-acute institutions

Prescription Use ___X___ AND/OR Over –The-Counter Use _____

(Part 21 CFR 801 Subpart D) (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)

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Division Sign-Off

Office of Device Evaluation

Evaluation and Safety

510(k) **K103434**

L Arnoldsen

(Division Sign-Off)

Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K103434