K112271

FEB 16 2012

Section 5: **510(k) SUMMARY**
[As required by 21 CFR §807.92(c)]

Date Prepared: July 27, 2011

Official Contact:
Alex 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 Willow™ Nasal Mask

Device Common Name/
Classification Name: Vented Nasal Mask
Classification: 21 CFR §868.5905, 73 BZD (CLASS II)

Predicate Devices:

Manufacturer:	Resmed
Trade Name:	Mirage Swift II
510(k) Number:	K042403
Manufacturer:	Respironics
Trade Name:	ComfortLite 2
510(k) Number:	K082558
Manufacturer:	Fisher & Paykel
Trade Name:	Opus 360
510(k) Number:	K063036

Device Description:

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

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

Intended Use:

The Willow™ channels airflow noninvasively to a patient from a positive airway pressure (PAP) device or a bilevel system. The Willow™ is:

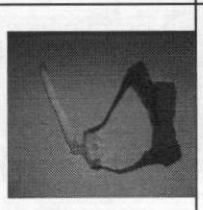
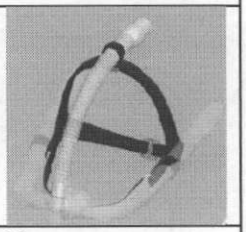
(1) to be used by adult patients (> 66lb / 30 kg) for the treatment of sleep disordered breathing, such as obstructive sleep apnea (OSA), for whom positive airway pressure has been prescribed.

(2) to be used for single-patient reuse in the home environment.

Contraindications: None

Technological Characteristics Comparison:

A comparative table of the Willow™ alongside the three identified predicate devices indicates that the Willow Nasal Pillows is substantially equivalent with the other three with respect to the form, performance, materials, structures and the ventilation characteristics.

Manufacturer	BMC	ResMed	Respironics	Fisher&Paykel
Model	Willow™ Nasal Pillows System	Mirage Swift II Nasal Pillows System (K042403)	ComfortLite™ 2 System (K082558)	Opus™ 360 Nasal Pillows Mask (K063036)
Pic				
Nasal pillows	Yes	Yes	Yes	Yes
With headgear	Yes	Yes	Yes	Yes
Latex free	Yes	Yes	Yes	Yes
Multi Size	Yes	Yes	Yes	Yes
Connector	22mm	22mm	22mm	22mm
Therapy Pressure	4-20cmH20	4-20cmH20	4-30cmH20	3-25cmH20
Intentional	4cmH20=20L/	4cmH20=20L	4cmH20=22L/min	5cmH20=22L/min

leak	min 10cmH20=31.5 L/min 20cmH20=45L/ min	/min 12cmH20=37 /min 20cmH20=49 L/min	12cmH20=34L/mi n 20cmH20=42L/mi n	11cmH20=33L/min 21cmH20=48L/min 25cmH20=52L/min
Resistance	1.0 cmH20 at 50L/min 3.1 cmH20 at 100L/min	0.4 cmH20 at 50L/min 1.6 cmH20 at 100L/min	NA	1.2 cmH20 at 50L/min 5.4 cmH20 at 100L/min
Dead Space	96ml	91ml	19-36ml(mask only)	22ml(mask only)

To verify the substantial equivalence claim, the Willow™ was performance bench tested against the ResMed Mirage Swift (K042043). The results of the performance bench testing, along with a description of the testing protocol are found at Appendix A. In terms of performance characteristics (i.e. passive exhalation port flow, resistance to flow, and dead space), the two devices are substantially equivalent.

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

3B Products, LLC
C/O Mr. Alex Lucio
Managing Partner
1142 N. Scenic Highway
Lake Wales, Florida 33853

FEB 16 2012

Re: K112271
Trade/Device Name: 3B Willow™ Nasal Mask
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator
Regulatory Class: II
Product Code: BZD
Dated: February 4, 2012
Received: February 9, 2012

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

Indications for Use

510(k) Number: **K112271**
Device Name: 3B Willow™ Nasal Mask

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(2) to be used for single-patient reuse in the home environment.

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)

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

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