K123789

510(k) SUMMARY

[As required by 21 CFR 807.92(c)]

MAR 2 9 2013

Date Prepared	March 28th, 2013
Submitter Name	Mr. Kim Kuan LEE
Official Contact	Mr. Jim Cassi Vice President - Quality Assurance Americas 9001 Spectrum Center Blvd San Diego CA 92123 USA Tel: (858) 836 6081
Device Trade Name	Swift™ FX Nano
Device Common Name/ Classification Name	Vented Nasal Mask; Accessory to Noncontinuous Ventilator (IPPB)
Classification	21 CFR 868.5905, 73 BZD (Class II)
Predicate Devices	Swift FX (K090244) Mirage FX (K102746) Ultra Mirage II (K050359)
Description	The Swift FX Nano provides an interface such that airflow from a positive pressure source is directed to the patient's nose. The mask is held in place with adjustable headgear that straps the mask to the face. Swift FX Nano is safe when used under the conditions and purposes intended as indicated in the labeling provided with the product. Swift FX Nano is a prescription device supplied non-sterile.
Intended Use	The Swift FX Nano channels airflow noninvasively to a patient from a positive airway pressure device such as a continuous positive airway pressure (CPAP) or bilevel device. The Swift FX Nano is: • to be used by patients (> 66 lbs / 30 kg) for whom positive airway pressure has been prescribed • intended for single-patient re-use in the home environment and multipatient re-use in the hospital/institutional environment.
Technological Characteristics comparison	*Comparison with predicate Swift FX* The new device and the predicate mask, provide a seal via silicone interface. The new device design incorporates a cushion that seals around the patient's nose whereas the predicate Swift FX design comprises pillows that seal under the nasal nares. Both masks are offered in various sizes to ensure adequate fit over the extended patient population. Both masks incorporate vent holes to provide continuous air leak to flush out and minimize the amount of CO_2 re-breathed 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 masks.

Both masks connect to a conventional air delivery hose between the mask and the positive airway-pressure source via standard conical connectors.

Both masks are constructed using molded plastic and silicone components and fabric / nylon headgear. All the components of both masks are fabricated using materials deemed safe. (ref: ISO 10993-1).

Materials that contact the heated humidified gas pathway are considered to be external communication permanent duration (tissue/bone/dentin). The biological tests for warm wet air path application, in accordance with FDA Guidance #G95-1 were:

- ISO 10993-3 Genotoxicity,
- ISO 10993-5 Cytotoxicity,
- ISO 10993-6 Implantation and
- ISO 10993-10 Sensitisation and Irritation.

The biological tests for materials considered to have permanent skin contact, in accordance with FDA Guidance #G95-1, were:

- ISO 10993-5 Cytotoxicity
- ISO 10993-10 Sensitisation and Irritation

In addition, development of the Swift FX Nano device complies with ISO 14971:2007, Medical devices - Application of risk management to medical devices.

Both the new mask and the predicate device are designed to operate on the same *Pillows*, *Mirage* or *Swift* ResMed flow generator settings. The pressure-flow characteristics and flow impedance of both devices are identical.

Both the new mask and the predicate device can be reused in the home and hospital / institution environment.

Technological Characteristics comparison

Comparison with predicate Mirage FX

The new device and the predicate Mirage FX mask provide a seal via a silicone interface that covers over and around the patient's nose. Both the new and predicate masks are offered in various cushion sizes to ensure adequate fit over the extended patient population.

Performance Data

Comparison with predicate Ultra Mirage II

The CO2 performance of the new device and the predicate device are substantially equivalent.

Clinical Data

Use of vented nasal masks with CPAP or Bilevel therapy is proven technology and is well accepted by the medical community. Bench testing is sufficient to demonstrate safety and efficacy of the new Swift FX Nano, as was the case with the predicate devices.

Substantial Equivalence Conclusion	The new Swift FX Nano is as safe and effective as the predicate devices: - it has the same intended use; - it has identical technological characteristics to the predicate devices; - the new device did not raise any new questions of safety or effectiveness; - it is at least as safe and effective as the predicate devices.

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

March 29, 2013

ResMed Limited
C/O Mr. Jim Cassi
Vice President
Quality Assurance Americas
9001 Spectrum Center Boulevard
SAN DIEGO CA 92123

Re: K123789
Trade/Device Name: Swift™ FX Nano
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: II
Product Code: BZD
Dated: February 22, 2013
Received: February 25, 2013

Dear Mr. Cassi:

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 -S 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

Indication for Use

510(k) Number (if known): K123789
Device Name: **Swift™ FX Nano**
Indication for Use

The Swift FX Nano channels airflow noninvasively to a patient from a positive airway pressure device such as a continuous positive airway pressure (CPAP) or bilevel system.

The Swift FX Nano is:

- to be used by patients (>66lb / >30kg) for whom positive airway pressure has been prescribed.
- intended for single patient re-use in the home environment and multipatient re-use in the hospital/institutional environment.

Prescription Use ___X___ AND/OR Over-The-Counter Use____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH; Office of Device Evaluation (ODE)

6th Dec, 2012

Albert E. Moyal -S (for LS)

c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300059331, cn=Albert E. Moyal -S 2013.03.28 15:57:05 -04'00'

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

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