K020641

OCT 29 2002

Non-confidential 510(k) Summary of Safety and Effectiveness

1. Applicant Name & Address

Worldwide Medical Technologies Inc.
3178 Keen Drive
Waycross, Georgia 31503.

2. Trade Name of Device

Spiritus™ Respiratory System

3. Common Name(s) of Device

Patient Interface Accessory

4. Classification Name

Accessory to the CPAP/BiPAP device
[VENTILATOR, NON-CONTINUOUS (RESPIRATOR)]

5. Classification & Classification Code

21 CFR 868.5905,73 BZD Class II.

6. Device Description

The device is a single-patient-use, patient interface accessory for patients receiving positive airway pressure treatment including CPAP and BiPAP and comprises the nasal/tubing assembly and associated headgear.

The nasal cannula protuberances fit into the patient's nares effecting a substantially airtight seal, facilitating the delivery of the positive airway pressure. Tubing is fitted to the nasal cannula via elbow connectors which may be used to secure the detachable headgear. The tubing fits to a "Y" connector to effect connection to the flow generator output tube.

The nasal cannula, tubing and connectors may be cleaned with mild soap and water for use by the same patient.

7. Intended Use

The Spiritus™ Respiratory System is a patient interface accessory intended for use with devices that administer CPAP (continuous positive airway pressure) and bi-level airway pressure in treating adult patients.

8. Predicate Device

Substantial equivalence is claimed to the Puritan-Bennett Airway Delivery & Management (ADAM) Nasal Ventilation, subject of 510(k) K900164.

9. Summary of Performance Testing

Performance was confirmed through the execution of flow resistance, enclosed volume, and intentional leak rate tests.

10. Conclusion

Based on the above, we conclude the Spiritus™ Respiratory System is substantially equivalent to predicate device, and is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 9 2002

Worldwide Medical Technologies, Incorporated
C/O Mr. Jonathan Lee
JSL Consulting Incorporated
138 Spartina Avenue
St. Augustine, Florida 32080

Re: K020641
Trade/Device Name: Spiritus™ Respiratory System
Regulation Number: 868.5905
Regulation Name: Noncontinuous Ventilator, Accessory
Regulatory Class: II
Product Code: BZD
Dated: October 7, 2002
Received: October 9, 2002

Dear Mr. Lee:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

U.S. Food and Drug Administration - Center for Devices and Radiological Health

510(k) Number (if known): K020641

Device Name: Spiritus™ Respiratory System

Indications for Use:

The Spiritus™ Respiratory System is a single-patient-use, patient interface accessory intended for use by patients who have been prescribed positive airway pressure treatment (PAP) including CPAP and BiPAP.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription use ✓

(Optional Format 3-10-98)

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

510(k) Number: K020641