K992384

DEC - 1 1999

510(k) Premarket Notification Summary of Safety and Effectiveness Information	CPAP/PRO®

Regulatory Authority: Safe Medical Devices Act of 1990, 21 CFR 807.92

1. **Device Name:**
   TRADE NAME: **CPAP/PRO® CPAP Interface**
   COMMON NAME: CPAP
   CLASSIFICATION NAME: Noncontinuous ventilator

2. **Establishment Name & Registration Number:**
   Name: STEVENSON INDUSTRIES, INC.
   Number: Pending

3. **Classification:**
   § 868.5905 (IPPB). (a) Identification. A noncontinuous ventilator (intermittent positive pressure breathing-IPPB) is a device intended to deliver intermittently an aerosol to a patient's lungs or to assist a patient's breathing. (b) Classification. Class II (performance standards).
   Product Code(s): 73BZD ~~& 76LRK~~
   Device Class: Class II ~~& unclassified~~
   Classification Panel: Anesthesia Devices Panel ~~& Dental Device Panel, respectively~~

4. **Contact Person:**
   Mr. Joseph L. Goldstein
   STEVENSON INDUSTRIES, INC.
   1515 Palisades Dr., Suite M
   Pacific Palisades, CA 90272-9906
   310.459.9393 - 310.459.1575 FAX

   Submission Correspondent:
   Mr. David W. Schlerf
   Buckman Company, Inc.
   200 Gregory Lane, Suite C-100
   925.356.2640 / 925.356.2654 FAX

6. **Description of the Device:**

The **CPAP/PRO® CPAP Interface** consists of a boil & bite type dental appliance or a bracket, which may be professionally fitted to a custom dental appliance. With either mouth appliance, a small bracket extends beyond the lips to attach to a pair of corrugated nasal tubes. The paired nasal tubes are made from corrugated polyethylene and are pressure tested. The paired tubes combine to form a "Y". The lower arm of which attaches to a CPAP machine using a fitting connected to standard respirator tubing. The upper arms of the "Y" shaped nasal tubes terminate in soft silicone nasal inserts. The inserts provide a soft, comfortable seal against the nostrils.

The **CPAP/PRO®** consists of the following major components:
1. Boil & bite molded dental appliance with integral tubing clamp.
2. **CPAP/PRO®** tubing clamp for use with professionally fitted dental appliance.
3. Polycarbonate dual lumen respiratory tubing connector.
4. Corrugated 15mm (nominal diameter) polyethylene tubing with 1/8th " vent holes.
5. Silicone elastomer nasal inserts.
6. Dual lumen (polycarbonate) tubing/appliance bracket .

7. **Comparison to Predicate Device(s):**

CPAP/PRO® CPAP Interface may be directly contrasted with the following equivalent devices:

1. ***SoftNair™*** by Vital Signs, Inc.
2. ***Adam CPAP Circuit*** by Nellcor Puritan-Bennett

The ***SoftNair™*** and ***Adam CPAP Circuit*** are the most like the **CPAP/PRO®** in terms of design, materials and method of use. Comparative testing has been conducted and demonstrates that, in terms of airflow and dead-space, the **CPAP/PRO®** is the functional equivalent of both devices.

8. **Packaging:**

Plastic bags, peel pouches, and clear tubes are used to contain the individual device components. The packaging selected for use is sufficient to identify, protect and transport the devices safely. Shipper materials are standard, paper fiber industry typical bulk box-type shipper packaging.

9. **Sterilization/Re-sterilization:**

The device and its components are packaged in "clean only" condition but are free of manufacturing debris and residue. Each component is inspected after processing to evaluate and document the removal of manufacturing residue and debris. However, it is recommended the device be removed from it's shipping and packing materials, washed and rinsed thoroughly before use.

10. **Conclusion:**

Based on the materials, intended uses, design, comparison testing, long standing safe and effective use of the CPAP nasal interface, the **CPAP/PRO** unit is equivalent to the referenced legally marketed comparison devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 1 1999

Mr. David W. Schlerf
Stevenson Industries, Inc.
c/o Buckman Company Incorporated
200 Gregory Lane, Suite C-100
Pleasant Hill, CA 94523-3389

Re: K992384
CPAP/PRO® CPAP Interface
Regulatory Class: II (two)
Product Code: 73 BZD
Dated: September 14, 1999
Received: September 16, 1999

Dear Mr. Schlerf:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. 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"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

for Carole C. Carey

Celia M. Witten, Ph.D., M.D.
Acting Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K992384

Device Name: CPAP/PRO® CPAP Interface
CPAP/PRO® Antisnoring Device

Indications For Use:

The **CPAP/PRO® CPAP Interface** is intended to treat adult obstructive sleep apnea(OSA).

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K992384

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109) (Optional format 1-2-96)