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

October 17, 2014

Stevenson Industries, Incorporated
Ms. Serrah Namini
Regulatory
780 Chambers Lane, #200
Simi Valley, CA 93065

Re: K141152
Trade/Device Name: CPAP/Pro® Interface with Advantage
Regulation Number: 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: Class II
Product Code: BZD
Dated: September 15, 2014
Received: September 16, 2014

Dear Ms. Namini:

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 contact 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. 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,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
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 STATEMENT

510(k) Number (if known): K141152

Device Name: CPAP/Pro Interface with Advantage ™

Indication for Use: The Advantage ™ is used with commercially available CPAPs to reduce or alleviate nighttime snoring and obstructive sleep apnea (OSA) for adults weighing more than 66 lb (30 Kg) used at home, hospital or other clinical settings per order of a physician.

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Prescription Use: _X___ Or Over-The-Counter_ _ _
(Per 21 CFR 801.109) (Optional Format 1-2-96)

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

_____ _____ _____ _____ _____ _____

Concurrence of CDRH, Office of Device Evaluation (ODE)

Stevenson Industries, Inc.CPAP/PRO with Advantage™

510(k) Summary

- ***Summary Date:***

May 1, 2014

- ***Submitter Information:***

Mr. Joseph Goldstein, President
Stevenson Industries, Inc.
780 Chambers Ln #200
Simi Valley, CA 93065
Tel: 800-538-8803
Fax: 805-426-3551

- ***Primary Contact:***

Serrah Namini, Regulatory
naminib@yahoo.com
(949) 734-3570

- ***Trade/ Device Name:***

CPAP/Pro Interface with Advantage ™

- ***Common Name:***

CPAP interface

- ***Device Classification Name:***

Ventilator, Non-Continuous (Respirator)

- ***Regulation:***

21 CFR 868.5905

- ***Regulatory Class:*** Class II

- **Primary Product Code(s):** BZD

- **Predicate Information**

CPAP/PRO by Stevenson Industries, Inc. ; K992384

- ***Device Description***

The CPAP/Pro Interface with Advantage ™ is available for upper and lower teeth. As such, it utilizes two typical “boil & bite” devices to be placed in patient’s upper and lower dental arches. They are then affixed to one another anteriorly to limit the mouth

opening, while still permitting a degree of mouth opening through spacers and resiliency.

The upper member is slotted and slides forward and backward on a fixed post for patient comfort. Additionally, it allows lateral movement with the post as a pivot point. The CPAP/Pro Interface with Advantage ™, similar to chin straps or mouth tapes, minimizes the mouth breathing but provides comfort and ease of use for patients. The device is used for adult patients at home or clinical facilities, such as hospitals or sleep labs.

- **Indications for Use**

The Advantage ™ is used with commercially available CPAPs to reduce or alleviate nighttime snoring and obstructive sleep apnea (OSA) for adults weighing more than 66 lb (30 Kg) used at home, hospital or other clinical settings per order of a physician.

- **Technological Characteristics**

Technological characteristics of the device is the same as predicate. The additional accessory, Advantage ™ , uses the same design and materials as the upper mouthpiece provided with the predicate. It is available with upper and lower mouthpiece with a post and without a bracket. The post allows a comfortable forward/backward movement as well as some lateral side –to- side capability. No new questions of safety and effectiveness were introduced.

- **Performance Data**

All applicable tests were completed and passed. Bench testing was performed and confirms that the device meets design requirements and specifications. Validation was also satisfactory completed. Post-market studies of CPAP/Pro has supported the safety and effectiveness of the product. The Advantage ™ has also been validated to demonstrate product equivalency with the predicate.

- **Substantial Equivalence**

Based on the information drawn from the Testing and Validation as well as the risk assessment, it is demonstrated that the device is substantially equivalent and performs as well as the predicate device.

Feature	**CPAP/PRO (K992384)**	**New device CPAP/PRO with Advantage™**
Intended Use	To reduce or alleviate night time snoring and obstructive sleep apnea (OSA) for adult patients	Similar

	for use at home or clinical setting; for adult patients (>66lb/30kg)	
Materials	Teflon, polyethylene, silicone, elastomer, styrene, nylon, EVA thermoplastic	Similar
Design CPAP nasal	Nasal cannula CPAP	Similar
Design Oral Appliance	Dental appliance holds nasal CPAP cannula. Appliance positions jaw and holds nasal CPAP cannula (including upper mouthpiece)	Same with additional mouth-piece (Advantage™) for minimizing mouth-breathing
Performance standard	ASTM (ex: D1238)	Similar
Reusable	Yes (single patient)	Similar
Method of cleaning/disinfection	Wash with warm water and detergent followed by surface disinfection (See Instruction for Use)	Similar
Manufacturer	Stevenson Industries, Inc.	Same

- **Conclusion**

The primary difference is the use of Advantage™, the oral appliance for minimizing mouth-breathing. Previously a dental appliance held the nasal CPAP cannula. Which, positions jaw and holds nasal CPAP cannula (including upper mouthpiece). The results of the testing support the claim that the Advantage™ is substantially equivalent to the predicate.

The device functions, the scientific concepts that form the basis for the device, and the significant physical and performance characteristics of the device, such as device design, material used, and physical properties remain similar as the predicate. The Advantage™ is substantially equivalent to its predicate and reference devices.