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

December 15, 2016

Bluesom
Paul Dryden
Consultant
BlueSom
24 Rue Leon Gaumont
Orvault, 44700 FR

Re: K162192
Trade/Device Name: BluePro®
Regulation Number: 21 CFR 872.5570
Regulation Name: Intraoral Devices for Snoring and Intraoral Devices for Snoring and Obstructive Sleep Apnea
Regulatory Class: Class II
Product Code: LRK
Dated: November 14, 2016
Received: November 15, 2016

Dear Mr. Paul Dryden:

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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K162192

Device Name

BluePro®

Indications for Use *(Describe)*

The BluePro® is a mandibular repositioning device intended to reduce or alleviate night-time snoring and mild to moderate obstructive sleep apnea in adult patients 18 years or older.

Type of Use *(Select one or both, as applicable)*

XX Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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K162192
510(k) Summary
7-Dec-16

BLUESOM
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Official Contact:	Erwan Floch - General Manager
Proprietary or Trade Name:	BluePro®
Common/Usual Name:	Intra-oral appliance
Classification Name:	LRK - Device, anti-snoring, Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea 21 CFR 872.5570, Class 2
Predicate Device:	K113569 – Apnea Sciences – ApneaRx

Device Description
The BluePro® oral appliance design concept is based upon the use of a standard set of upper and lower trays, referred also as splints in documentation, that are then customized for fit by a dentist. The design is commonly referred to as a Mandibular Repositioning Device (MRD).

The principle of advancing a lower or upper tray so that it advances the mandible for the treatment of snoring and / or mild to moderate obstructive sleep apnea is well known and there are a number of predicate devices.

Indications for Use
The BluePro® is a mandibular repositioning device intended to reduce or alleviate night-time snoring and mild to moderate obstructive sleep apnea in adult patients 18 years or older.

Contraindications
The device is contraindicated for patients who:
- have central sleep apnea
- have severe respiratory disorders
- have loose teeth or advanced periodontal disease
- have loose dental work, dentures, or other oral conditions which would be adversely affected by wearing dental appliances
- are under 18 years of age

Warnings
Use of this device may cause:
- tooth movement or changes in dental occlusion
- gingival or dental soreness
- pain or soreness to the temporomandibular joint
- obstruction of oral breathing
- excessive salivation
- excessive dry mouth
- loosening of dental restorations
- loosening of teeth

Environment of Use
Home, Dental and Physician offices, and Sleep laboratories

Predicate Device Comparison:

Table 1 compares the predicate and the subject device.

	Predicate ApneaRx K113569	**Subject Device BluePro® K162192**
Indications for Use	The Apnea Sciences Corporation "ApneaRx" is intended for use on adult patients 18 years of age or older as an aid for the reduction of mild to moderate obstructive sleep apnea (OSA), and/or snoring.	The BluePro® is a mandibular repositioning device intended to reduce or alleviate night-time snoring and mild to moderate obstructive sleep apnea in adult patients 18 years or older.
Environments of use	Home, dental and Physician offices, Sleep laboratories	Home, dental and Physician offices, Sleep laboratories
Patient Population	Adult patients 18 years and older	Adult patients 18 years and older
Contraindications	• have central sleep apnea • have severe respiratory disorders • have loose teeth or advanced periodontal disease • are under 18 years of age	• have central sleep apnea • have severe respiratory disorders • have loose teeth or advanced periodontal disease • are under 18 years of age
Prescription	Prescription use	Prescription use
Single patient, multi-use	Yes	Yes
Limitation of duration of use	No limitation	No limitation
Principle of operation / means of mandibular advancement	Adjustment of the relative position of the trays by the use of fixed advancement.	Adjustment of the relative position of the trays by the use of fixed advancement.
Fixed tray sizes	Yes	Yes
Method to advance the mandible	Integral interlocking advancement method	Integral interlocking advancement method
Allows lateral and vertical movement	Yes	Yes
Employs boil and bite design	Yes	Yes
Maximum adjustment by the user	10 mm	10 mm
Works by holding lower jaw forward	Yes	Yes
Cleaned by simple rinsing with water	Yes	Yes
Cleaning with toothbrush	Yes	Yes
Biocompatibility and Patient contact	Surface Contacting, Mucosal membrane, with duration of use prolonged > 24 hours < 30 days, per FDA Guidance Class II Special Controls Guidance Document: Intraoral Devices for Snoring and/or Obstructive Sleep Apnea; Guidance for Industry and FDA dated 11/12/2002	ISO 10993 Cytotoxicity Sensitization Irritation Surface Contacting, Mucosal membrane, with duration of use prolonged > 24 hours < 30 days, per FDA Guidance Intraoral Devices for Snoring and/or Obstructive Sleep Apnea dated 11/12/2002
Age testing		Yes
Real-time clinical experience		Yes

The BluePro® is viewed as substantially equivalent to the predicate device because:

Indications – Similar to predicate – ApneaRx – K113569; indicated for treating snoring and mild to moderate obstructive sleep apnea (OSA).
Discussion – The indications for use between the subject device and predicate are similar and therefore they can be found as substantially equivalent.

Technology / Principle of Operation – Similar to predicate – ApneaRx – K113569. Both devices use separate pre-formed trays with a means to advance the mandible / lower jaw.
Discussion – Both devices use separate pre-formed trays with a means to advance the mandible / lower jaw are similar and therefore they can be found as substantially equivalent.

Environment of Use – Similar to predicate – ApneaRx – K113569. They are used in Home, Dental offices, Physician offices, Sleep laboratories.
Discussion – Both devices have similar environments of use and therefore they can be found as substantially equivalent.

Patient Population – Similar to predicate – ApneaRx – K113569. 18 years and older
Discussion – The patient population is similar and therefore they can be found as substantially equivalent.

Non-clinical performance testing
Commercial experience
The BluePro® has been marketed outside the US since October 2014. The results of this experience support the substantial equivalence of the BluePro® for the intended use, as compared to the predicate device.

The observations support:

- Cleaning via rinsing with water and use of a toothbrush
- Real-time clinical experience from sales outside the US
- Mechanical and durability after real-time use plus simulated 1 year use via the Braem testing

Biocompatibility of Materials
All the materials are considered per FDA G95-1 as Surface Contacting, Mucosal membrane, with duration of use prolonged > 24 hours < 30 days, per *FDA Guidance Class II Special Controls Guidance Document: Intraoral Devices for Snoring and/or Obstructive Sleep Apnea; Guidance for Industry and FDA* dated 11/12/2002

Based upon the Guidance the ISO 10993-1 testing would be:

- Cytotoxicity
- Sensitization
- Irritation

Testing was performed on finished, final devices.

Clinical
No clinical testing.

Discussion of Differences and Conclusion

The subject and predicate devices share equivalent intended use, that of treating snoring and mild to moderate obstructive sleep apnea (OSA). Both the subject and predicate devices share equivalent technology, in that they both use separate pre-formed trays with a means to advance the mandible / lower jaw. Both the subject and predicate devices employ a boil and bite design to provide a custom impression for each patient. Both devices have similar environments of use, patient populations and biocompatibility.

Any differences between the subject and predicate devices are not significant and does not affect the substantial equivalence of the proposed device to the predicate device.

Substantial Equivalence Conclusion

Based upon the performance testing and comparison to the legally marketed predicate device for indications for use, technology, and performance we believe we have demonstrated that the BluePro® is substantially equivalent to the predicate device.