August 16, 2018

InnoMed Healthscience, Inc.
% Paul Dryden
Consultant
InnoMed Healthscience, Inc. c/o ProMedic, LLC
131 Bay Point Dr. NE
Saint Petersburg, FL 33704

Re: K180619
Trade/Device Name: Bongo
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: OHP
Dated: July 16, 2018
Received: July 17, 2018

Dear 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely yours,

Srinivas Nandkumar -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180619

Device Name
Bongo

Indications for Use *(Describe)*
Bongo is indicated for use in the treatment of mild to moderate obstructive sleep apnea (OSA) in adults >66 lbs.

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Date Prepared: August 10, 2018

InnoMed Healthscience, Inc.
1701 W. Hillsboro Blvd.
Suite 303
Deerfield Beach, FL 33442

Official Contact: Javier Collazo
General Manager and Vice President
Tel - 954.773.9656

Proprietary or Trade Name: Bongo

Common/Usual Name: Expiratory resistance valve, intranasal, for obstructive sleep apnea

Classification Name: 21CFR 872.5570
ProCode – OHP
Class II

Predicate Device: Ventus ProVent (K102404)

Device Description: The Bongo intranasal appliance is a simple device which is placed just inside the nostrils. The device directs expiratory flow through small vent ports which increases intranasal pressure similar to the expiratory portion of the breathing cycle during use of the predicate device. The Bongo consists of valve assemblies coupled with nasal inserts. The Bongo has soft nasal inserts to form a seal within the nasal openings. The nasal inserts are offered in various sizes.

Indications for Use: Bongo is indicated for use in the treatment of mild to moderate obstructive sleep apnea (OSA) in adults >66 lbs.

Patient Population: For adults (>66 lbs.) with mild to moderate OSA.

Environments of Use: Home use, hospitals, and sleep laboratories

Attributes	**Proposed Bongo**	**Predicate** **Ventus ProVent (K102404)**	**Comments**
Indications for Use	For use in the treatment of mild to moderate obstructive sleep apnea (OSA).	For use in the treatment of obstructive sleep apnea (OSA).	Similar
Patient Population	Adults (>66 lbs. / 30 kg.)	Not specified	Similar
Environment of Use	Home Hospitals Sleep Laboratories	Not specified	Similar
Duration of Use	Single patient, multi-use Used on a daily basis	Single patient, disposable Used on a daily basis	Bongo can be cleaned and reused
Prescriptive	Yes	Yes	Identical
Technology / Mode of Operation			
Creation of expiratory positive airway pressure	During exhalation the valves close, directing air through small ports, increasing resistance. This resistance creates EPAP (Expiratory Positive Airway Pressure), which props open the airway until you inhale again.	During exhalation the valves close, directing air through small ports, increasing resistance. This resistance creates EPAP (Expiratory Positive Airway Pressure), which props open the airway until you inhale again.	Identical
Sealing method	Soft nasal inserts	Adhesive seals around the nostril openings	Similar
Features			
Multiple sizes of nasal inserts	Yes	Not required	Similar
One expiratory flow / resistance	Yes	Yes	Similar
Single Patient	Yes, but may be cleaned and reused	Yes, but is single use disposable	Similar
Technical Specifications / Performance Testing			
Inhalation Resistance	Comparative inhalation resistance testing was performed evaluating the subject device and the predicate device at various flow rates.	Comparative inhalation resistance testing was performed evaluating the subject device and the predicate device at various flow rates.	Similar inhalation resistance
Exhalation Flow (ml/sec) @ a given pressure	Comparative exhalation flow testing was performed evaluating the subject device and the predicate device at various pressures.	Comparative exhalation flow testing was performed evaluating the subject device and the predicate device at various pressures.	Similar exhalation flow
Classification of Patient Contacting Materials for Biocompatibility	ISO 10993-1 Surface Contact / External Communicating Permanent duration of use	ISO 10993-1 Surface Contact / External Communicating Permanent duration of use	Similar

Attributes	**Proposed Bongo**	**Predicate Ventus ProVent (K102404)**	**Comments**
Additional Non-clinical Testing	Age / Shelf-life Cleaning Drop test Environmental conditions Valve cycling	Not specified in 510(k) summary	Subject device meets its performance specifications
Clinical Testing	Subjects were evaluated under PSG and the results demonstrate that AHI was reduced with Bongo.	Available clinical data showed a reduction in AHI with the device.	Similar

The Bongo intranasal appliance is viewed as substantially equivalent to the predicate device because:

Indications –

- The Bongo is intended to be used in the treatment of mild to moderate OSA.
- The predicate ProVent (K102404) is intended to be used in the treatment OSA, therefore the indications for use are considered substantially equivalent.

Patient Population –

- The Bongo and the predicate ProVent (K102404) are both intended for adults (>66 lbs.).
- Therefore, the patient population is considered substantially equivalent.

Technology and Principle of Operation –

- The Principle of Operation is to create expiratory positive airway pressure (EPAP).
- The proposed Bongo and the predicate ProVent (K102404) employ similar technology, i.e., use of flap valves which open during inhalation and close during exhalation to create the EPAP.
- The principle of operation is considered substantially equivalent.
- The Bongo and the predicate ProVent (K102404) both have nasal insert portions that are placed into the nasal openings. The Bongo utilizes soft nasal inserts, which are offered in various sizes, to form a seal within the nasal openings. The predicate ProVent (K102404), which is offered in one size, utilizes adhesive to seal around the nasal openings.

Environment of Use –

- The devices are intended for use in the home, hospitals, and sleep laboratories.
- Substantially equivalent to predicate ProVent (K102404).

Non-clinical Testing –
Biocompatibility of Patient Contacting Materials –

- The materials have been tested per ISO 10993-1 and they have been used in legally marketed devices which have equivalent patient contact and duration of use.
- ISO 10993-1 would consider the type of patient contact as Surface Contact / mucosal and Externally Communicating / Tissue and permanent duration of use.

Performance Compared to the Predicate
Comparative testing was performed evaluating the Bongo vs. the predicate ProVent (K102404) for the key performance specifications which could demonstrate substantial equivalence. These test included:

- Inhalation Resistance
- Expiration Flow rate

A summary of the testing was presented in the above table.

- The results of the comparative performance testing demonstrated that the Bongo is substantially equivalent to the predicate ProVent (K102404).

In addition to these comparative tests we also performed testing to demonstrate that the Bongo meets its performance specifications after being subjected to aging, environmental temperature changes, cleaning, and being dropped.

- The results support that the Bongo meets it performance specifications and is not affected by aging or cleaning.

Clinical Testing -
A prospective, non-randomized, open label, single-center clinical study was performed.

The clinical study had ten (N=10) patients who completed the study, with seven patients responding with AHI reduction using the Bongo. For the patients (N=10):

- The mean diagnostic AHI was 15.7 and the mean AHI for the final PSG with Bongo was 7.1.
- The median diagnostic AHI was 15.4 and the median AHI for the final PSG with Bongo was 7.0.

The results demonstrated that AHI was significantly reduced with the Bongo compared to the baseline diagnostic. There were no serious adverse events.

Discussion:
In comparing available clinical data for the predicate both the predicate and subject device reduced AHI with the device compared without the device. The reductions were substantially equivalent.

Substantial Equivalence Conclusion:
The sponsor has demonstrated through performance testing, design and features, non-clinical, and clinical testing that the proposed device does not raise different risks of safety and effectiveness compared to the predicate and are substantially equivalent.