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

September 26, 2014

Atos Medical AB
Mr. Ferenc Dahnér
Regulatory Affairs Manager
Kraftgatan 8
Hörby, SE SE-24222

Re: K141380
Trade/Device Name: Provox FreeHands FlexiVoice
Regulation Number: 21 CFR 874.3730
Regulation Name: Laryngeal prosthesis (Taub Design)
Regulatory Class: Class II
Product Code: EWL
Dated: August 23, 2014
Received: August 27, 2014

Dear Mr. Dahnér,

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 yours,

Eric A. Mann -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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141380

Device Name
Provox FreeHands FlexiVoice

Indications for Use *(Describe)*
The Provox FreeHands FlexiVoice combines pulmonary rehabilitation using a Heat and Moisture Exchanger with voice rehabilitation using an Automatic Speaking Valve or Manual Occlusion, in laryngectomized patients using a voice prosthesis.

The entire device is for single patient use and the HME-part is for single use, i.e, it has to be exchanged at least every 24 hours.

Environments of use include: Hospitals, ICU, sub-acute care institutions and home.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Section 5 – 510(k) Summary

Atos Medical AB
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Official Contact: Ferenc Dahnér – Regulatory Affairs Manager

Proprietary or Trade Name: Provox FreeHands FlexiVoice

Common/Usual Name: Speaking Valve

Classification Class II - 21 CFR 874.3730

Classification Name/Code: EWL – Prosthesis, laryngeal (taub)

Device: Provox FreeHands FlexiVoice

Predicate Devices: Atos Medical – Provox FreeHands HME (K022125)

Device Description:
The Provox FreeHands consists of two functional units that work together, a speech valve unit in a reusable housing and a disposable Provox FreeHands HME Cassette, which is connected to the lower part of the valve housing before it is ready to use.

The speech valve unit allows hands-free tracheostoma occlusion for voice prosthesis users. It has three interchangeable membranes (Light, Medium and Strong).

The HME unit of the Provox® FreeHands HME® is a full heat-and-moisture-exchanger, which is used for partial restoration of the lost upper airway functions. It also separates the speech valve from direct contact with the airway and, thus, prevents mucous from being coughed into the valve part of the device. It also reduces the risk of inhalation of small particles, e.g., coming from a defective valve.

After proper adjustment and attachment of the speech valve unit and HME cassette, the completed Provox FreeHands HME is inserted into either Provox Adhesive base plate or Provox LaryTube with ring.

Indications for Use:
The Provox FreeHands FlexiVoice combines pulmonary rehabilitation using a Heat and Moisture Exchanger with voice rehabilitation using an Automatic Speaking Valve or Manual Occlusion, in laryngectomized patients using a voice prosthesis.

The entire device is for single patient use and the HME-part is for single use, i.e., it has to be exchanged at least every 24 hours.

Patient Population:
Laryngectomized patients using a voice prosthesis.

Environment of Use:
Environments of use include; Everyday environment. (Home, hospital etc.)

Contraindications:
The Provox FreeHands FlexiVoice is not intended to be used by patients unable to remove or operate the device.

Non Confidential Summary

Comparison to Predicate Device:

Attributes of predicates	Proposed Provox FreeHands FlexiVoice
Intended population: Laryngectomized patients using a voice prosthesis.	Same
Environments of use include; Everyday environment. (Home, hospital etc.).	Same
Eliminates the necessity of finger occlusion for the patient with a voice prosthesis.	Yes
Provides heat and humidity	Yes
Intended to connect to the Provox attachment devices	Yes
Intended for single patient use	Yes
HME exchanged at least every 24 h.	Same
Prescription	Yes
Standard 22 mm connectors	Same
Air pressure operated speech valve one-way, always open for inhalation	Same
Allows exhalation to atmosphere freely during normal breathing and in locked mode under all breathing circumstances.	Same
Method for diverting exhaled air through voice prosthesis: Turn top to activate air pressure operated speaking valve.	Same
Method to return too exhalation after speaking: breathe normally	Same
Materials HME: Calcium chloride treated polyurethane foam	Same
Speaking Valve: Silicone, plastic, titanium and a magnet alloy	Silicone and plastic

Summary of Non-Clinical Testing:
The following tests were performed to verify that Provox FreeHands FlexiVoice met applicable safety and performance requirements.

The main focus areas of testing were:

- Verification of the closing flow, opening pressure, cough-out pressure, moisture loss, airflow resistance and leakage test.
- Verification of attachment and detachment forces in the different interfaces including the durability of the devices.
- Simulated use of all FreeHands FlexiVoice products and their IFUs.
- Verification of FreeHands FlexiVoice products' function after fatigue test, climate testing, aging and transport.

In addition, risk management according ISO 14971 and simulated use testing (usability study) has been conducted.

A comparative analysis shows that the Provox FreeHands FlexiVoice closes at approximately the same flow rate as the predicate Provox FreeHands HME. Only a small adjustment has been made in the closing flow based on experience from usage of Provox FreeHands HME.

Additionally, moisture loss, flow resistance and air leakage of the two devices are very similar. The flow resistance of Provox FreeHands FlexiVoice is a bit lower than Provox FreeHands. This is also based on experience from usage of Provox FreeHands HME. We therefore conclude that key properties of the devices are equivalent in terms of working principle, safety and effectiveness.

Non Confidential Summary

Substantial Equivalence Conclusion:
There are no significant differences between the Provox FreeHands FlexiVoice compared to the predicate device in terms of indications, materials, design and operating principles.
Information presented in this submission supports that Provox FreeHands FlexiVoice is as safe and effective, and performs as well or better than the predicate device.

Atos Medical AB concludes that the Provox FreeHands FlexiVoice is substantially equivalent to the predicate device.