Section 5 – 510(k) Summary

JUN – 5 2009

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Official Contact: Ferenc Dahnér – Regulatory Affairs Manager

Proprietary or Trade Name: Provox® Vega™

Common/Usual Name: Voice Prosthesis

Classification Name/Code: EWL – Prosthesis, Laryngeal (Taub)

Device: Provox® Vega™

Predicate Devices: Atos – Provox2 Voice Prosthesis – K971244

Device Description:

The Provox Vega is a one-way valve (prosthesis) that keeps a TE-puncture open for speech, while reducing the risk of fluids and food entering the trachea. The Provox Vega voice prosthesis is not a permanent implant, and needs periodic replacement. The prosthesis is available in different diameters and several lengths. The device is made of silicone and fluoroplastic.

The Provox Vega package contains the following items:
- 1 Provox Vega voice prosthesis pre-loaded in a single-use SmartInserter, sterile
- 1 Provox Brush of a size corresponding to the voice prosthesis, non-sterile
- 1 Clinician Manual
- 1 Patient Manual
- 1 Provox Brush Instructions for Use

Indications for Use:

The Provox® Vega Voice Prosthesis is a sterile single use indwelling voice prosthesis intended for voice rehabilitation after surgical removal of the larynx (laryngectomy). Cleaning of the voice prosthesis is handled by the Patient while it remains in situ.

The Provox SmartInserter is a sterile single use device intended for anterograde replacement of the Provox Vega Voice Prosthesis. This replacement procedure is carried out by a medical doctor or a trained medical professional in accordance with local or national guidelines.

The Provox SmartInserter is not intended to be used for insertion of a voice prosthesis in a freshly made puncture.

Environments of use for the Provox® Vega Voice Prosthesis include – hospitals, sub-acute care institutions and home.
For the Provox SmartInserter environments of use include – hospitals and sub-acute care institutions.

Patient Population: For patients who have got their larynx surgically removed.

Environment of Use: Hospitals, sub-acute care institutions and home.

Contraindications: There are no known contraindications for use or replacement of the prosthesis among patients already using prosthetic voice rehabilitation.

Summary of substantial equivalence

Specification	Predicate Provox2 Voice Prosthesis – (K971244)	Proposed Device
Indications for use	The Provox2 Voice Rehabilitation System is intended for use in surgical, prosthetic voice restoration after total laryngectomy. The prosthesis may be inserted by the physician at the time of the total laryngectomy (primary puncture), or at a later date (secondary puncture), or may be used to replace the present prosthesis.	The Provox® Vega Voice Prosthesis is a sterile single use indwelling voice prosthesis intended for voice rehabilitation after surgical removal of the larynx (laryngectomy). Cleaning of the voice prosthesis is handled by the Patient while it remains in situ. The Provox SmartInserter is a sterile single use device intended for anterograde replacement of the Provox Vega Voice Prosthesis, and must be used by a trained and experienced clinician. The Provox SmartInserter is not intended to be used for insertion of a voice prosthesis in a freshly made puncture.
Environment of Use	Hospitals, sub-acute care institutions and home	Identical
Patient Population	For patients who have got their larynx surgically removed (laryngectomy)	Identical
Contra-indications	There are no known contraindications for use or replacement of the prosthesis among patients already using prosthetic voice rehabilitation.	Identical
Diameters; **Shaft** **Tracheal Flange** **Esophageal flange**	 22,5Fr (7,5mm) 13,6mm 14,3mm	 Identical 13,1mm / 16,9mm (oval) 14,5mm
Shaft lengths (mm)	4.5, 6, 8, 10, 12.5, 15mm	4, 6, 8, 10, 12.5, 15mm
Materials; **Voice Prosthesis**	Components: Silicone and fluoroplastic. Adhesive: Silicone Adhesive	Components: Identical Adhesive: Silicone Adhesive
Materials; **Loading tube**	Loading tube: Polypropylene Loading tube lubricant: Silicone oil	Loading tube: Polyethylene Folding device: Polypropylene Guide: Polypropylene Loading tube lubricant: Fluorsilicone oil
Materials; Inserter	Polypropylene	Polyoxymethylene, glass reinforced
Storage conditions	Standard 22°C ± 20 °C, 45% rH ± 35% rH, not direct sunlight	Identical

Differences between Other Legally Marketed Predicate Devices

There are no significant differences that affect the safety or effectiveness of the intended device as compared to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Atos Medical AB
c/o Mr. Ferenc Dahnér
Regulatory Affairs Manager
P.O. Box 183
SE-242 22 Hörby - Sweden

JUN - 5 2009

Re: K090455
Trade/Device Name: Provox® Vega™
Regulation Number: 21 CFR 874.3730
Regulation Name: Laryngeal prosthesis (Taub design)
Regulatory Class: Class II
Product Code: EWL
Dated: May 12, 2009
Received: May 14, 2009

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.

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 go to http://www.fda.gov/cdrh/comp/ for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Kesia Alexander 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

K090455

510(k) Number: K090455

Device Name: Provox® Vega™

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Prescription Use XX (Part 21 CFR 801 Subpart D) **or** **Over-the-counter use** __ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Daniel C Clapper

(Division Sign-Off)
Division of Ophthalmic and Ear, Nose and Throat Devices

510(k) Number K090455