



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 6 1997

Eddy Åberg
Technical Manager
Atos Medical
P.O. Box 183
Kraftgaten 8
S242-22 Hörby
Sweden

Re: K971244
Provox 2 Voice Prosthesis System
Dated: March 18, 1997
Received: April 3, 1997
Regulatory class: II
21 CFR 874.3730/Procode: 77 EWL

Dear Mr. Åberg:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591 for Radiology devices, or 594-4613 for Ear, Nose and Throat devices. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ATOS MEDICAL

June 4, 1997

20.2 INDICATIONS FOR USE, PROVOX® PROSTHESIS SYSTEM

Premarket Notification 510 (k) Number: K 971244

The PROVOX Voice Rehabilitation System has exactly the same indications for use as the original PROVOX and is intended for use in prosthetic voice restoration after total laryngectomy. The prosthesis can be inserted at the time of laryngectomy (primary puncture), or at a later date (secondary puncture), or to replace another similar prosthesis. Replacement is performed in an antegrade way, using the components accompanying the PROVOX2 device (Insertion tool). The development of an antegrade replacement method (through the tracheostoma) was a logical development since the retrograde replacement method (using a guide wire) is often uncomfortable for the patient. The PROVOX2 can be used in primary or secondary TE-puncture procedures if it is used with the PROVOX GuideWire, the Trocar and Cannula, and the Pharynx Protector components of the PROVOX Voice Rehabilitation System.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use OR Over-The-Counter Use

(Per 21 CFR 801.109)

David A. Seymour (Optional Format 1-2-96)
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K971244

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