K991587

JUN 25 1999

HELIX MEDICAL, INC
510(k) SUMMARY
BLOM-SINGER INDWELLING 2000 VOICE PROSTHESIS

I. NAME OF SUBMITTER

Helix Medical, Inc.
1110 Mark Avenue
Carpinteria, CA 93013
Contact person: Cynthia Anderson

Establishment Registration Number: 2025182

II. DEVICE NAME AND CLASSIFICATION

Proprietary Name: Blom-Singer Indwelling 2000 Voice Prosthesis
Common or Usual Name: Voice Prosthesis

Class II; 21 CFR 874.3730
The Blom-Singer Indwelling 2000 Voice Prosthesis is neither a life-supporting nor a life-sustaining device. It is not considered an implant.

III. PREDICATE DEVICES

The **Blom-Singer Indwelling 2000 Voice Prosthesis** and its accessory devices are substantially equivalent in design and indications for use to the following devices currently in commercial distribution:

• InHealth Indwelling Voice Prosthesis, Helix Medical, Carpinteria, CA; K932120

• Provox2 Voice Rehabilitation System, ATOS Medical AB, Hörby, Sweden; K971244

The **Blom-Singer Indwelling 2000 Voice Prosthesis Accessory Devices** are either Class I devices not subject to 510(k) or are substantially equivalent to the following devices:

• InHealth Blom-Singer Low Pressure Voice Prosthesis Gel Cap Insertion System, Helix Medical, Carpinteria, CA; K930105 (Inserter Tool and Gel Caps)

• InHealth Blom-Singer Flushing Pipet, Helix Medical, Carpinteria, CA; K932163 (Flushing Device)

• InHealth Blom-Singer Indwelling Plug Insert Accessory Device, Helix Medical, Carpinteria, CA; K945288 (Plug Insert)

IV. DESCRIPTION

The design of the Blom-Singer Indwelling 2000 Voice Prosthesis is substantially equivalent to the current Blom-Singer Indwelling Low Pressure Voice Prosthesis. Both devices are

manufactured sterile and nonsterile, out of medical grade silicone elastomer, and are comprised of a body with an outer esophageal flange and a tracheal flange with a strap. Both devices utilize a flap valve to control the passage of air through the device. The Blom-Singer Indwelling 2000 has the addition of an assembled cartridge, consisting of a valve and a valve seat, to optimize the valve performance and longevity. The valve now has an additive which has demonstrated antibacterial properties in *in-vitro* studies.

To aid in placing the gel cap onto the device, the esophageal flange on the outer portion of the device has been modified. The esophageal flange now has contoured areas, which allow the flange to fold along the contours for easy insertion into a gel cap for atraumatic placement of the device.

V. INTENDED USE

The Blom-Singer Indwelling 2000 Voice Prosthesis is for voice rehabilitation following total laryngectomy where placement of the voice prosthesis is done by a clinician.

The Blom-Singer Indwelling 2000 Voice Prosthesis may be placed at the time of surgery or may be placed at a later date secondary to the laryngectomy.

VI. TECHNOLOGICAL CHARACTERISTICS

The Blom-Singer Indwelling 2000 Voice Prosthesis is provided for the same indications for use as its predicate devices, the Blom-Singer Indwelling Low Pressure Voice Prosthesis and the Provox 2 Voice Prosthesis. All three devices are indwelling devices designed to provide voicing after total laryngectomy. The devices are placed in a surgically-created fistula between the trachea and esophagus in order to divert air through the prosthesis valve to created voicing. The use of an indwelling device means that routine removal for cleaning by the patient is not necessary, thus making it easier for the patient to maintain the device while reducing the risk of accidental dislodgment of the device.

The Blom-Singer Indwelling 2000 Voice Prosthesis has been modified from its predicate device by the addition of the assembled cartridge, consisting of a valve and valve seat, to isolate the valve and valve seat from tissue contact. The valve has an antibacterial additive.

Functional equivalency tests have been performed on the two Blom-Singer prostheses, which demonstrate the equivalency of the valve performance with the two designs.

Accessory Devices: The Blom-Singer Indwelling 2000 Voice Prosthesis will be offered with the following accessories as optional items:

The Inserter Tool and Gel Caps

Blom-Singer Flushing Device

Blom-Singer Brush

Blom-Singer Plug Insert

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 25 1999

Ms. Cynthia Anderson
Director, Regulatory Affairs/Quality Assurance
Helix Medical, Inc.
11100 Mark Avenue
Carpinteria, CA 93013

Re: K991587
Trade Name: Blom-Singer Indwelling 2000 Voice Prosthesis
Regulatory Class: II
Product Code: 77 EWL
Dated: May 6, 1999
Received: May 7, 1999

Dear Ms. Anderson:

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 current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) 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) 594-4613. 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,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K991587

Include the following "Indications For Use" page that contains the applicant's name, name of the device and the intended use of the device. The information, data and labeling claims in the entire the 510(k) submission must support and agree with the "indications for use" statement.
*For a new submission, do NOT fill in the 510(k) number blank.

INDICATIONS FOR USE

Applicant: Helix Medical, Inc.

510(k) Number (if known): N/A* K991587

Device Name: Blom-Singer Indwelling 2000 Voice Prosthesis.

Indications For Use:

The Blom-Singer Indwelling 2000 Voice Prosthesis is for voice rehabilitation following total laryngectomy where placement/replacement of the voice prosthesis is done by a clinician. The Blom-Singer Indwelling 2000 Voice Prosthesis may be placed at the time of surgery or may be placed at a later date secondary to the laryngectomy.

(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 _____
Per 21 CFR 801.109

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K991587