K082206

HELIX
MEDICAL

SEP - 4 2008

Helix Medical, LLC
510(k) Summary
Blom-Singer Dual Valve Voice Prosthesis

I NAME OF SUBMITTER

Helix Medical, LLC
1110 Mark Ave.
Carpinteria, CA 93013
Contact Person: Cynthia Anderson
Establishment Registration Number: 2025182

II DEVICE NAME AND CLASSIFICATION

Proprietary Name: Blom-Singer Dual Valve Voice Prosthesis
Common or Usual Name: Voice Prosthesis

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

III PREDICATE DEVICES

K932120, Blom-Singer Indwelling Low Pressure Voice Prosthesis, April 15, 1994

K945287, InHealth Blom-Singer Indwelling Valved Insert, December 9, 1994

K991587, Blom-Singer Indwelling 2000, June 25, 1999

Related accessories being provided with product:

-inserter stick
-flushing device
-flange introducer
-gel caps
-lubricant

IV DESCRIPTION

The Blom-Singer Dual Valve Indwelling Voice Prosthesis is provided for the same indications for use as the other Blom-Singer Indwelling Voice Prosthesis product lines. The Dual Valve Indwelling Voice Prosthesis has been modified from its predicate devices by the addition of a second valve intended to continue to function when leakage occurs in the primary valve.

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510(k) Summary cont'd.

V INTENDED USE

The Blom-Singer Indwelling voice prosthesis is indicated for tracheoesophageal voice restoration following total laryngectomy, when placement, or replacement, of an indwelling voice prosthesis is performed by a qualified, trained medical professional.

VI TECHNOLOGICAL REQUIREMENTS

The Blom-Singer Dual Valve Indwelling Voice Prosthesis is provided for the same indications for use as its predicate devices, the Blom-Singer Indwelling 2000 Voice Prosthesis, the Blom-Singer Indwelling Low Pressure Voice Prosthesis, and the InHealth Blom-Singer Indwelling Valved Insert. All three devices are indwelling devices primarily made of silicone, designed to provide voicing after total laryngectomy. The voice prostheses are placed in a surgically-created fistula between the trachea and esophagus in order to divert air through the prosthesis valve to create 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 Dual Valve Indwelling Prosthesis has been modified from its predicate devices by the addition of a second valve, consisting of a valve and valve seat, intended to continue to function when leakage occurs in the primary valve. The prosthesis is still primarily silicone. A second modification is the introduction of a slight tension in the voice prosthesis strap when loaded on the inserter with a gel cap containing the prosthesis' esophageal flange. When the gel cap dissolves the inserter moves forward, indicating flange deployment.

Functional equivalency tests have been performed on the Blom-Singer prostheses, which demonstrate the equivalency of the valve performance with the predicate designs. Non-clinical tests referenced for a determination of substantial equivalence are Airflow, Pressure Decay, Flange Retention Force, Valve Attachment Integrity and Inserter Deployment. The conclusions drawn from the nonclinical tests demonstrate that the device is safe, as effective, and performs as well or better than the predicate devices.

Accessory Devices: The device will be offered with the following accessories: inserter stick, flushing device, flange introducer, gel caps, and lubricant.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Helix Medical, LLC
c/o Ms. Cynthia Anderson
VP, Regulatory Affairs
1110 Mark Avenue
Capinteria, CA 93013

Re: K082206
Trade/Device Name: Blom-Singer Dual Valve Voice Prosthesis
Regulation Number: 21 CFR 874.3730
Regulation Name: Laryngeal prosthesis (Taub design)
Regulatory Class: Class II
Product Code: EWL
Dated: July 31, 2008
Received: August 5, 2008

Dear Ms. Anderson:

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 such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,

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

K082206

Indications for Use Statement

510(k) Number: not yet assigned K082206

Device Name: Blom-Singer Dual Valve Voice Prosthesis

Indications for Use:

The Blom-Singer Indwelling voice prosthesis is indicated for tracheoesophageal voice restoration following total laryngectomy, when placement, or replacement, of an indwelling voice prosthesis is performed by a qualified, trained medical professional.

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 DFR 801.109)

David C Chang

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

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