K974311

510(k) Summary of Safety and Effectiveness

MAR - 4 1998

Trade Name: Vocal Cord Medialization (VoCoM®) System
Common Name: Vocal Cord Medialization Implants
Classification Name: Ear, Nose, and Throat Synthetic Polymer Material (§ 874.3620)

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The VoCoM System is substantially equivalent to the Montgomery® Thyroplasty Implant System manufactured by Boston Medical Products, Inc. These devices have the same indications for use, medialization of a paralyzed vocal cord. The VoCoM implant and shim are made from Hydroxylapatite, a widely accepted material for Otolaryngological use. The Montgomery Thyroplasty Implant System implants are made of silicone.

The VoCoM System is also substantially equivalent to the Hydroxylapatite Bone Graft Material manufactured by Smith & Nephew, Inc., ENT Division. Both devices are made of hydroxylapatite. The VoCoM device is intended for medialization of a paralyzed vocal cord, while the Hydroxylapatite Bone Graft Material is intended to augment bony deficiencies or reconstruction of bony defects in head and neck applications.

The differences between the VoCoM system and the predicate devices should not affect the safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 4 1998

Deborah Arthur
Smith & Nephew, Inc.
Director or Regulatory/Clinical Affairs
and Quality Assurance
ENT Division
2925 Appling Rd.
Bartlett, TN 38133

Re: K974311
Vocal Cord Medialization (VoCoM®) System
Dated: February 17, 1998
Received: February 20, 1998
Regulatory class: II
21 CFR 874.3620/Procode: 77 KHJ

Dear Ms. Arthur:

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/dsma/dsmamain.html".

Sincerely yours,

Lillian Yin

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

510(k) Number: K974311

Device Name: **Vocal Cord Medialization (VoCoM®) System**

Indications For Use:

The Smith & Nephew, Inc., ENT Division, Vocal Cord Medialization System is indicated for medialization thyroplasty in patients with unilateral vocal cord paralysis to improve voice quality.

David A. Zeyman

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K974311

Prescription Use ✓ OR Over-The-Counter Use —
(per 21 CFR 801.109)