K962693

AUG - 9 1996

SMDA Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Product: Montgomery Radiopaque Laryngeal Keel

Description: The Laryngeal Keel is an umbrella-shaped device designed to conform to the anatomy of the anterior commissure. The keel is available is sizes 12mm, 14mm, and 16mm.

Indication For Use:

1. To repair simple anterior glottic stenosis due to anterior commissure web formation.

2. To prevent anterior glottic stenosis in situations where anterior commissure stenosis is likely to occur (eg, following extralaryngeal or endolaryngeal trauma with loss of anterior commissure).

3. To prevent the anterior glottic stenosis immediately following removal of the Montgomery Laryngeal Stent.

Predicate Device: Montgomery Laryngeal Keel.

Testing: Finished device samples passed cytotoxicity testing and were determined to be non-reactive and non-cytotoxic based on Elution Test, USP 23.

Submitted by: _____, PRESIDENT
Stuart K. Montgomery, President

Date: 7/10/96

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Boston Medical Products
Mr. Stuart K. Montgomery
President
117 Flanders Road
Westborough, Massachusetts 01581

JAN 1 0 2017

Re: K962693
Trade/Device Name: Montgomery Raiopaque Laryngeal Keel
Regulation Number: 21 CFR 874.3620
Regulation Name: Ear, Nose, and Throat Synthetic Polymer Material
Regulatory Class: Class II
Product Code: FWN
Dated: July 10, 1996
Received: July 11, 1996

Dear Mr. Montgomery:

This letter corrects our substantially equivalent letter of August 9, 1996.

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 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 contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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/MedicalDevices/Safety/ReportaProblem/default.htm 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 Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

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

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FDA/CDRH/ODE/DMC

Boston Medical Products, Inc.
117 Flanders Road
Westborough, MA 01581
ATT: Stuart K. Montgomery (508) 898-9300 ext. 240
FAX 8982373

510(k) Number (if known): K962693

Device Name: **Montgomery Radiopaque Laryngeal Keel**

Indications For Use:

1. To repair simple anterior glottic stenosis due to anterior commissure web formation.

2. To prevent anterior glottic stenosis in situations where anterior commissure stenosis is likely to occur (eg, following extralaryngeal or endolaryngeal trauma with loss of anterior commissure).

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K962693

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ___

(Optional Format 1-2-96)