K978317

510(k) Summary
Boston Medical Products, Inc.
Montgomery® Thyroplasty Implant System
(per 21 CFR 807.92)

SEP 18 1997

1. **DATE OF PREPARATION:** June 18, 1997

2. **SPONSOR/APPLICANT:** Boston Medical Products, Inc.
117 Flanders Road
Westborough, MA 10581

3. **CONTACT NAME:** Stuart Montgomery, President
Telephone: 508-898-9300

4. **DEVICE NAME:**

Trade/Proprietary Name:	Montgomery® Thyroplasty Implant System
Common/Usual Name:	Thyroplasty Implant and Accessories
Classification Name:	Ear, nose, and throat synthetic polymer material and manual surgical instruments

5. **IDENTIFICATION OF THE PREDICATE OR LEGALLY MARKETED DEVICE(S) TO WHICH EQUIVALENCE IS BEING CLAIMED:**

The Montgomery® Thyroplasty Implant is substantially equivalent to legally marketed silicone block, as carved at the time of surgery, specifically the following:

· Duralastic Silicone	Allied Biomedical	K955368, K955370, K955433
· Silicone Block	Bentec Medical	Not identified
· Silicone Block	Xomed	K970910

6. **DEVICE DESCRIPTION**

The Montgomery® Thyroplasty Implant System consists of the Implant and associated accessory surgical instruments which are used for selection of implant size and for the surgical thyroplasty procedure.

The Montgomery® Thyroplasty Implant is a one-piece device consisting of a three-tiered base and an obtuse triangular top. It is provided in five sizes for males and five for females. The difference in size relates to the height of the triangular portion of the Implant. There is a single base size for all five male implants and a smaller base size for all five female implants.

Accessories to the System include the sterile, single use Measuring Kits for selection of the correct implant size at the time of surgery, the Procedure Kit for determining the correct position of the Implant and marking the window in the thyroid cartilage, and various elevators, hooks, etc. which are provided to facilitate both the surgical procedure and the placement of the Implant.

7. INTENDED USE

The Montgomery® Thyroplasty Implant is indicated for medialization thyroplasty in patient with unilateral vocal cord paralysis to improve quality of vocalization.

8. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The Montgomery® Thyroplasty Implant is equivalent to silicone block, as carved at the time of surgery. It is composed of an inner, softer top and firm base which secures the implant in the thyroid laminotomy. Bentec silicone block is available in four durometers: Soft (20A), Medium (35A), Firm (50A), and Extra firm (65A). Allied Biomedical silicone block is provided as Very soft (5A), Soft (10A), Medium (20-30A), and Hard (40A and above). While Bentec and Allied Biomedical product designations for durometer are similar, they are not equal. Unlike the use of solid silicone block of a single durometer, the durometers used for the Montgomery Thyroplasty Implant are more consistent with the characteristics of the surrounding tissue.

The Montgomery® Thyroplasty Implant is radiopaque, while the radiopacity of the Bentec and Allied Biomedical silicone blocks is not specified. Bentec does not specify coloration or radiopacity of their block. Allied Biomedical silicone block is generally supplied clear; however custom colors of white, opaque, and flesh tone are available as special order items.

The Montgomery® Thyroplasty Implant is supplied sterile. The sterility status of Bentec and Allied Biomedical silicone block is not specified in product literature.

While the Montgomery® Thyroplasty Implant is molded, implants fashioned from Bentec and Allied Biomedical silicone block must be carved at time of surgery. Appropriate sizing of the Montgomery Thyroplasty Implant is accomplished using the sterile, single use, and disposable Measuring Kits. Sizing of silicone block-derived medialization implants is dependent on surgeon skill.

Tolerances for the Montgomery® Thyroplasty Implant provide consistency across devices whereas the precision for medialization thyroplasty implants carved from silicone block is limited and dependent on surgeon skill.

The surface of the Montgomery® Thyroplasty Implant has smooth edges and radii. The finish quality of medialization thyroplasty implants which are fashioned from silicone block at the time of surgery is variable and dependent on surgeon skill.

Based on the above discussion of the use of carved silicone block for medialization thyroplasty, Boston Medical Products, Inc. believes that the Montgomery® Thyroplasty Implant is substantially equivalent to solid silicone block as carved at the time of thyroplasty surgery and that differences do not adversely effect safety and effectiveness.

9. CLINICAL STUDIES

Clinical data for a cohort of 44 patients treated with the Montgomery® Thyroplasty Implant demonstrate that the device is safe, as evidenced by the low number of complications, and effective for improvement of voice quality, as demonstrated by responses to the patient survey, acoustic analysis, and stroboscopy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Boston Medical Products, Inc.
c/o Rosina Robinson, RN, MEd, RAC
Staff Consultant
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, MA 02760

Re: K972317
Montgomery® Thyroplasty Implant System
Dated: June 19, 1997
Received: June 20, 1997
Regulatory Class: II
21 CFR 874.3620/Procode: 77 KHJ

SEP 18 1997

Dear Ms. Robinson:

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 requirement, 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,

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 (if known): K972317

Device Name: Boston Medical Products, Inc. Montgomery® Thyroplasty Implant System

Indications For Use:

The Boston Medical Products, Inc. Montgomery® Thyroplasty Implant is indicated for medialization thyroplasty in patients with unilateral vocal cord paralysis to improve voice quality.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ____

David A. Seymour
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K972317