



Boston
Medical
Products

K972096

JUL 15 1997

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.

Description: The Bivalve Nasal Splint, constructed of medical grade flouroplastic (i.e. Teflon®), is designed to provide septal support and reduce or prevent adhesions between the septum and lateral nasal wall following surgery. The splint is available in two sizes, standard and large, with two thicknesses (0.25mm and 0.50mm) for each size. The standard size is for routine use, while the large size can be be trimmed for individual applications. Both sizes feature a lengthwise slit facilitating placement and removal, and pre-formed suture holes for stabilizing the splint.

The Bivalve Nasal Splint is supplied sterile, two splints per package, five packages per box.

Indication For Use: To provide septal support and reduce or prevent adhesions between the septum and lateral nasal wall following surgery.

Contraindications: None known.

Predicate Device: Product Nos. 20-10650, 20-10655, 20-10660, and 20-10665 manufactured by Invotec International, Inc., 11243-1 St. John's Industrial Parkway South, Jacksonville, FL 32246.

Testing: Device is constructed using well-established medical grade flouroplastic..

Submitted by: Stuart K. Montgomery, President

Date: 6/3/97



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Stuart K. Montgomery
President
Boston Medical Products, Inc.
117 Flanders Road
Westborough, MA 01581 USA

Re: K972096
Bivalve Nasal Splint
Dated: June 3, 1997
Received: June 4, 1997
Regulatory class: Unclassified
Procode: 77 LYA

JUL 15 1997

Dear Mr. Montgomery:

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

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Westborough, MA 01581
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510(k) Number (if known): K972096

Device Name: Bivalve Nasal Splint

Indications For Use: To provide septal support and reduce or prevent adhesions between the septum and lateral nasal wall following surgery.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

David A. Bergmann
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K972096