Boston Medical Products

K972092

JUL - 8 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 Nasal Airway Splint is designed provide septal support and allow nasal breathing post-operatively through the integral airway. The splints can be sutured through the pre-formed holes in the anterior tips for stabilization. The Nasal Airway Splints are packaged as a pair (left side and right side) and are supplied sterile, ready to use.

Indication For Use: To maintain a nasal airway while providing septal support following surgery.

Contraindications: None known.

Predicate Device: Product No. 20-10500 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 silicone.

Submitted by: _____ PRESIDENT
Stuart K. Montgomery, President

Date: 6/3/97

Boston Medical Products, Inc.
117 Flanders Road, Westborough, MA 01581 USA
CUSTOMER SERVICE: 1-800-433-BMPI (2674)
Tel: 508-898-9300 Fax: 508-898-2373

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 8 1997

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

Re: K972092
Nasal Airway Splint
Dated: June 3, 1997
Received: June 4, 1997
Regulatory class: Unclassified
Procode: 77 LYA

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

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

510(k) Number (if known): K972092

Device Name: Nasal Airway Splint

Indications For Use: To maintain a nasal airway while providing septal support 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 ✓ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K972092