K980679

APR - 3 1998

510(k) Summary of Safety and Effectiveness

Submitter: Biomet, Inc.
P.O. Box 578
Airport Industrial Park
Warsaw, IN 46581-0587

Contact Person: Mary L. Verstynen

Product Code: 76LYC

Device Name: Endobon®

Endobon® is used in the following dental and/or oral surgical procedures:

- alveolar ridge augmentation/reconstruction
- filling of resection defects in benign bone tumor, bone cysts, or other defects in the alveolar ridge or wall
- filling of periodontal bone pockets in the jaw (granules I)
- filling bone defects after apicetomy
- filling alveoli after tooth extraction

Endobon® is available in pre-formed shapes (i.e. blocks or cylinders) and granules sizes. This material is intended to fill voids or defects in bone and should not be used in non-periodontal mandibular applications.

Endobon® is a porous hydroxyapatite ceramic made from bovine cancellous bone. Hydroxyapatite (pentacalcium hydroxide [tris] phosphate) is both the main constituent of this ceramic bone substitute and a major constituent of the inorganic phase of human and animal bone. Endobon® is considered non-resorbable and is used to permanently fill or reconstruct bony defects. Use of hydroxyapatite ceramics as bone substitutes are well documented in the literature. In vitro and in vivo studies demonstrate that Endobon® has good biocompatibility and well tolerated by the human body.

The efficacy of Endobon® is based on biomechanical testing and clinical documentation. Clinical, radiologic, and histologic findings from clinical trials demonstrate the biocompatibility of Endobon® and confirmed its suitability for the desired indications.

The safety and effectiveness of Endobon® as a bone substitute has been determined in extensive preclinical studies and with over five years of clinical experience.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 3 1998

Mr. Mary L. Verstynen
Clinical Research Manager
Biomet® Incorporated
P.O. Box 587
Warsaw, Indiana 46581-0587®

Re: K980679
Trade Name: Endobon
Regulatory Class: II
Product Code: LYC
Dated: February 19, 1998
Received: February 20, 1998

Dear Ms. Verstynen:

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. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and 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, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (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 section 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

On August 16, 1993 the Final Rule for Device Tracking was published in the Federal Register, pages 43442-43455 (copy enclosed). Be advised that under Section 519(e) of the Act as amended by the Safe Medical Devices Act of 1990, FDA has identified the above device as a device which requires tracking. Because the device is subject to tracking, you are required to adopt a method of tracking that follows the devices through the distribution chain and then identifies and follows the patients who receive them. The specific requirements of the regulation are found in 21 CFR 821 as described in the August 16, 1993 Federal Register beginning on page 43447.

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) 594-4692. 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,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K980679

DEVICE NAME: Endobon

INDICATIONS FOR USE:

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- alveolar ridge augmentation/reconstruction
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- filling of periodontal bone pockets in the jaw (granules I)
- filling bone defects after apicetomy
- filling alveoli after after tooth axtraction

This product should not be used in non-periodontal mandibular applications.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use yes (Per 21 CFR 801.109) OR Over-The-Counter-Use No (Optional Format 1-2-96)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control, and General Hospital Devices
510(k) Number K980679