K962548

AUG - 5 1997

510(K) SUMMARY
for
ETEX α-BSM™ Bone Substitute Material Kit

1. DATE PREPARED

June 21, 1996

2. SPONSOR INFORMATION

Address ETEX Corporation
38 Sidney Street, Suite 370
Cambridge, MA 02139

Telephone: (617)577-7270

Contact: DoSuk D. Lee, Ph.D.

3. DEVICE NAME

Proprietary Name:	α-BSM™ Bone Substitute Material Kit
Common/Usual Name:	Bone Graft Material
Classification Name:	Endosseous Implant for Bone Filling and /or Augmentation

4. DEVICE DESCRIPTION AND INTENDED USE

α-BSM™ Bone Substitute Material Kit is a synthetic, calcium phosphate hydroxylapatitic material intended to aid in the healing of periodontal bone wall defects, to reduce alveolar bone pocket depth and increase alveolar bone thickness and height, to aid in gain in clinical attachment and for repair of cysts or other defects in the alveolar ridge or wall. α-BSM™ Bone Substitute Material Kit is provided in dry white powder form, it contains no pyrophosphates or amorphous tricalcium phosphate. The device is mixed with sterile water or saline just prior to its application to the desired periodontal defect.

5. PREDICATE DEVICES

α-BSM™ Bone Substitute Material Kit is substantially equivalent to devices currently in U.S. commercial distribution which are claassified as endosseous implant for bone filling and/or augmentation. Examples of other such products include OsteoGen® (manufactured by Impladent, Ltd.) and HAPSET® (manufactured by Lifecore Biomedical). All three products are forms of apatitic calcium phosphate with similar performance in the body.

6. DEVICE TESTING

Testing of α-BSM™ Bone Substitute Material was designed to characterize the finished material and assure the biocompatibility of the device. Biocompatibility testing included Skin Irritation, Sensitization, Acute Systemic Toxicity, Pyrogenicity, and Rabbit IM. Additionally, elemental analysis, x-ray diffraction (XRD), Fourier Transform Infrared (FTIR) Spectroscopy and sterility testing (USP 23) demonstrated that the device conforms to ASTM Standard F 1185 for Composition of Ceramic Hydroxylapatite for Surgical Use and that the material is sterile.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 5 1997

DoSuk D. Lee, Ph.D.
Etex Corporation
38 Sidney Street, Suite 370
Cambridge, Massachusetts 02139

Re: K962548
Trade Name: BSM Bone Substitute Material Kit
Regulatory Class: Unclassified
Product Code: LYC
Dated: December 17, 1996
Received: December 23, 1996

Dear Dr. Lee:

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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) 594-4618. 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 at (301) 443-6597.

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

PREMARKET NOTIFICATION

DEVICE NAME AND INTENDED USE STATEMENT

Device Name: **α-BSM™ Bone Substitute Material Kit**

510(k) Number: **K962548**

Indications/ Intended Uses:

α-BSM™ Bone Substitute Material is a synthetic calcium phosphate hydroxylapatitic material intended to aid in the healing of periodontal bone wall defects, extraction socket defects, and for repair of cysts or other defects in the alveolar ridge or wall.

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

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number: K962548

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ or Over-the -Counter Use _____