K102812

5. 510(k) Summary

5.1 510(k) Summary – Beta-bsm

DEC - 3 2010

Submitter:
ETEX Corporation
38 Sidney Street
Cambridge, MA 02139
Registration No.: 1225112
Owner/Operator No.: 9014709

Contact Person:
Christopher Klaczyk
Regulatory Affairs Manager
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Date Prepared: September 27, 2010

Product Code(s): LYC (21 CFR 872.3930)

Device Class: II (21 CFR 872.3930)

Classification Panel: Dental

Classification Name: Bone Grafting Material, Synthetic (21 CFR 872.3930)

Proprietary Name: Beta-bsm Injectable Bone Substitute Material

Predicate Device(s): Beta-bsm Injectable Bone Substitute Material (cleared for Dental and Maxillofacial indications per K091729)
Beta-bsm Injectable Bone Substitute Material (alternate Hydration Solution cleared for Orthopedic indications per K101557)

Device Description: Beta-bsm Injectable Bone Substitute Material is a synthetic, biocompatible bone graft substitute material. At the time of use, the powder component is combined with a specified volume of mixing solution and mixed to form a paste. Mixing is facilitated by a syringe-to-syringe mixing system. The resulting paste can be administered to the treatment site under direct visualization using the syringe or manual application. The material can be shaped into a desired form *in-situ* prior to implantation. After the paste is applied to the treatment site, it hardens at body temperature and converts to an apatitic calcium phosphate material. The end

product, poorly crystalline hydroxyapatite (PCHA), is of low crystalline order with a similar chemical and crystalline structure to that of natural bone minerals. Beta-bsm Injectable Bone Substitute Material is an osteoconductive material that is resorbed and replaced by natural bone over time.

Intended Use:

Beta-bsm Injectable Bone Substitute Material is an implantable synthetic calcium phosphate bone graft material that forms a nano-crystalline matrix that resorbs and is replaced with new bone during the healing process. It is indicated for use in filling and/or augmentation of bone voids, gaps or defects that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone.

Beta-bsm Injectable Bone Substitute Material is intended to be used in bony voids or gaps to fill and/or augment dental intraosseous, intraoral and maxillofacial defects. These defects include, but are not limited to, periodontal/infrabony defects; alveolar ridge augmentation (osteotomy, apicoectomy, cystectomy); dental extraction sites (ridge maintenance, implant preparation/placement); sinus lifts; cystic defects; craniofacial augmentation.

Technological Characteristics:

Characteristic	Subject	Predicate
Biomaterial	Proprietary calcium phosphate formula	Proprietary calcium phosphate formula
Hydration Media (provided)	0.9% sodium chloride solution conforming with the monograph for 0.9% Sodium Chloride Injection USP	0.9% Sodium Chloride Injection USP
Hydration Media (not provided)	None	None
Sterilization	Gamma irradiation	Gamma irradiation

Materials: Synthetic calcium phosphate

Non-Clinical Test: Testing consistent with *Class II Special Controls Guidance Document: Dental Bone Grafting Material Devices* (dated April 28, 2005) has been submitted.

Clinical Test: Per *Class II Special Controls Guidance Document: Dental Bone Grafting Material Devices* (dated April 28, 2005), clinical testing is not required for the subject devices.

Conclusions: Based upon our assessment of the performance data, the revised device is safe and effective for its intended use and performs as well as the predicate device.

K102812

5.2 510(k) Summary – Gamma-bsm

Submitter: ETEX Corporation
38 Sidney Street
Cambridge, MA 02139
Registration No.: 1225112
Owner/Operator No.: 9014709

DEC - 3 2010

Contact Person: Christopher Klaczyk
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Date Prepared: September 27, 2010

Product Code(s): LYC (21 CFR 872.3930)

Device Class: II (21 CFR 872.3930)

Classification Panel: Dental

Classification Name: Bone Grafting Material, Synthetic (21 CFR 872.3930)

Proprietary Name: Gamma-bsm Moldable Bone Substitute Material

Predicate Device(s): Gamma-bsm Moldable Bone Substitute Material (cleared for Dental and Maxillofacial indications per K091729)
Gamma-bsm Moldable Bone Substitute Material (alternate Hydration Solution cleared for Orthopedic indications per K101557)

Device Description: Gamma-bsm Moldable Bone Substitute Material is a synthetic, biocompatible bone graft substitute material. At the time of use, the powder component is combined with a specified volume of mixing solution and mixed to form aTraditional 510(k) Submission –Bone Grafting Material putty. The resulting putty is administered to the treatment site by manual application. The material can be shaped into a desired form *in-situ* prior to implantation. After the putty is applied to the treatment site, it hardens at body temperature and converts to an apatitic calcium phosphate material. The end product, poorly crystalline hydroxyapatite (PCHA), is of low crystalline order with a similar chemical and crystalline structure to that of natural

bone minerals. Gamma-bsm Moldable Bone Substitute Material is an osteoconductive material that is resorbed and replaced by natural bone over time.

Intended Use: Gamma-bsm Moldable Bone Substitute Material is an implantable synthetic calcium phosphate bone graft material that forms a nano-crystalline matrix that resorbs and is replaced with new bone during the healing process. It is indicated for use in filling and/or augmentation of bone voids, gaps or defects that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone.

Gamma-bsm Moldable Bone Substitute Material is intended to be used in bony voids or gaps to fill and/or augment dental intraosseous, intraoral and maxillofacial defects. These defects include, but are not limited to, periodontal/infrabony defects; alveolar ridge augmentation (osteotomy, apicoectomy, cystectomy); dental extraction sites (ridge maintenance, implant preparation/placement); sinus lifts; cystic defects; craniofacial augmentation.

Technological Characteristics:

Characteristic	Subject	Predicate
Biomaterial	Proprietary calcium phosphate formula	Proprietary calcium phosphate formula
Hydration Media (provided)	0.9% sodium chloride solution conforming with the monograph for 0.9% Sodium Chloride Injection USP	0.9% Sodium Chloride Injection USP
Hydration Media (not provided)	Autologous whole blood, autologous bone marrow aspirate	Autologous whole blood, autologous bone marrow aspirate
Sterilization	Gamma irradiation	Gamma irradiation

Materials: Synthetic calcium phosphate

Non-Clinical Test: Testing consistent with *Class II Special Controls Guidance Document: Dental Bone Grafting Material Devices* (dated April 28, 2005) has been submitted.

Clinical Test: Per *Class II Special Controls Guidance Document: Dental Bone Grafting Material Devices* (dated April 28, 2005), clinical testing is not required for the subject devices.

Conclusions: Based upon our assessment of the performance data, the revised device is safe and effective for its intended use and performs as well as the predicate device.

K102812

5.3 510(k) Summary – EquivaBone

Submitter: ETEX Corporation
38 Sidney Street
Cambridge, MA 02139
Registration No.: 1225112
Owner/Operator No.: 9014709

DEC - 3 2010

Contact Person: Christopher Klaczyk
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Date Prepared: September 27, 2010

Product Code(s): NUN (21 CFR 872.3930)

Device Class: II (21 CFR 872.3930)

Classification Panel: Dental

Classification Name: Bone Grafting Material, Human Source (21 CFR 872.3930)

Proprietary Name: EquivaBone Osteoinductive Bone Graft Substitute

Predicate Device(s): EquivaBone Osteoinductive Bone Graft Substitute (cleared for Dental and Maxillofacial indications per K091729)
EquivaBone Osteoinductive Bone Graft Substitute (alternate Hydration Solution cleared for Orthopedic indications per K101557)

Device Description: EquivaBone is a biocompatible bone graft substitute material consisting of synthetic calcium phosphate, carboxymethyl cellulose (CMC) and human demineralized bone matrix (DBM). It is supplied in a single use kit as Traditional 510(k) Submission –Bone Grafting Material sterile powders and hydration solution that are mixed together at the time of use in the operating room to form flowable putty which is implanted manually or can be extruded through a syringe. After implantation the product hardens at body temperature and resorbs and remodels during the healing process. Each lot of DBM contained within EquivaBone is assayed for osteoinductive potential in an athymic nude mouse model. This may or may not be predictive of EquivaBone osteoinductivity in humans.

Intended Use:

EquivaBone Osteoinductive Bone Graft Substitute is an implantable synthetic calcium phosphate bone graft material that forms a nano-crystalline matrix combined with demineralized bone matrix that resorbs and is replaced with new bone during the healing process. It is indicated for use in filling and/or augmentation of bone voids, gaps or defects that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone.

EquivaBone Osteoinductive Bone Graft Substitute is intended to be used in bony voids or gaps to fill and/or augment dental intraosseous, intraoral and maxillofacial defects. These defects include, but are not limited to, periodontal/infrabony defects; alveolar ridge augmentation (osteotomy, apicoectomy, cystectomy); dental extraction sites (ridge maintenance, implant preparation/placement); sinus lifts; cystic defects; craniofacial augmentation.

Technological Characteristics:

Characteristic	Subject	Predicate
Biomaterial	Proprietary calcium phosphate formula, carboxymethyl cellulose (CMC), demineralized bone matrix (DBM)	Proprietary calcium phosphate formula, carboxymethyl cellulose (CMC), demineralized bone matrix (DBM)
Hydration Media (provided)	0.9% sodium chloride solution conforming with the monograph for 0.9% Sodium Chloride Injection USP	0.9% Sodium Chloride Injection USP
Hydration Media (not provided)	Autologous whole blood, autologous bone marrow aspirate	Autologous whole blood, autologous bone marrow aspirate
Sterilization	Gamma irradiation	Gamma irradiation

Materials:

Synthetic calcium phosphate, sodium carboxymethyl cellulose (CMC) and demineralized bone matrix (DBM)

Non-Clinical Test:

Testing consistent with *Class II Special Controls Guidance Document: Dental Bone Grafting Material Devices* (dated April 28, 2005) has been submitted.

Clinical Test: Per *Class II Special Controls Guidance Document: Dental Bone Grafting Material Devices* (dated April 28, 2005), clinical testing is not required for the subject devices.

Conclusions: Based upon our assessment of the performance data, the revised device is safe and effective for its intended use and performs as well as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Christopher Klaczyk
Regulatory Affairs Manager
ETEX Corporation
38 Sidney Street
Cambridge, Massachusetts 02139

JAN 12 2011

Re: K102812
Trade/Device Name: Beta-bsm Injectable Bone Substitute Material
Gamma-bsm Moldable Bone Substitute Material
EquivaBone Osteoinductive Bone Graft Substitute
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: II
Product Code: NUN, LYC
Dated: November 3, 2010
Received: November 5, 2010

Dear Mr. Klaczyk:

This letter corrects our substantially equivalent letter of December 3, 2010.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval (PMA). 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 (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications For Use

4.1 Indications For Use – Beta-bsm

510(k) Number (if known): K102812

Device Name: Beta-bsm Injectable Bone Substitute Material

Indications for Use:

Beta-bsm Injectable Bone Substitute Material is an implantable synthetic calcium phosphate bone graft material that forms a nano-crystalline matrix that resorbs and is replaced with new bone during the healing process. It is indicated for use in filling and/or augmentation of bone voids, gaps or defects that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone.

Beta-bsm Injectable Bone Substitute Material is intended to be used in bony voids or gaps to fill and/or augment dental intraosseous, intraoral and maxillofacial defects. These defects include, but are not limited to, periodontal/infrabony defects; alveolar ridge augmentation (osteotomy, apicoectomy, cystectomy); dental extraction sites (ridge maintenance, implant preparation/placement); sinus lifts; cystic defects; craniofacial augmentation.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
510(k) Number: K102812

(Division Sign-Off)

Division of Anesthesiology, General Hos

Infection Control and Dental Devices

510(k) Number:

4.2 **Indications For Use – Gamma-bsm**

510(k) Number (if known): K102812

Device Name: Gamma-bsm Moldable Bone Substitute Material

Indications for Use:

Gamma-bsm Moldable Bone Substitute Material is an implantable synthetic calcium phosphate bone graft material that forms a nano-crystalline matrix that resorbs and is replaced with new bone during the healing process. It is indicated for use in filling and/or augmentation of bone voids, gaps or defects that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone.

Gamma-bsm Moldable Bone Substitute Material is intended to be used in bony voids or gaps to fill and/or augment dental intraosseous, intraoral and maxillofacial defects. These defects include, but are not limited to, periodontal/infrabony defects; alveolar ridge augmentation (osteotomy, apicoectomy, cystectomy); dental extraction sites (ridge maintenance, implant preparation/placement); sinus lifts; cystic defects; craniofacial augmentation.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
510(k) Number: K102812

(Division Sign-Off)
Division of Anesthesiology, General Hospi...
Infection Control and Dental Devices
510(k) Number: _____

4.3 **Indications For Use – EquivaBone**

510(k) Number (if known): K102812

Device Name: EquivaBone Osteoinductive Bone Graft Substitute

Indications for Use:

EquivaBone Osteoinductive Bone Graft Substitute is an implantable synthetic calcium phosphate bone graft material that forms a nano-crystalline matrix combined with demineralized bone matrix that resorbs and is replaced with new bone during the healing process. It is indicated for use in filling and/or augmentation of bone voids, gaps or defects that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone.

EquivaBone Osteoinductive Bone Graft Substitute is intended to be used in bony voids or gaps to fill and/or augment dental intraosseous, intraoral and maxillofacial defects. These defects include, but are not limited to, periodontal/infrabony defects; alveolar ridge augmentation (osteotomy, apicoectomy, cystectomy); dental extraction sites (ridge maintenance, implant preparation/placement); sinus lifts; cystic defects; craniofacial augmentation.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control and Dental Devices
510(k) Number: K102812

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