K101557

5. 510(k) Summary

JUL - 1 2010

5.1 510(k) Summary – Beta-bsm

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: June 28, 2010

Product Code(s): MQV (21 CFR 888.3045)

Classification Name: Resorbable Calcium Salt Bone Void Filler Device (21 CFR 888.3045)

Device Class: II (21 CFR 888.3045)

Classification Panel: Orthopaedics

FDA Panel Number: 87

Proprietary Name: Beta-bsm Injectable Bone Substitute Material

Predicate Device(s): Beta-bsm Injectable Bone Substitute Material (cleared as OssiFuse Bone Substitute Material, K072355)
α-BSM (K072636)

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 by injection 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 bone graft that is a synthetic calcium phosphate, poorly crystalline hydroxyapatite material intended for use in filling bone voids or defects of the skeletal system (i.e. the extremities, posterolateral spine and pelvis) 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 a bone graft substitute that resorbs and is replaced with new bone during the healing process.

Materials: Synthetic calcium phosphate

Performance Data: Regression testing consistent with *Class II Special Controls Guidance Document: Resorbable Calcium Salt Bone Void Filler Device; Guidance for Industry and FDA Staff* (dated June 2, 2003) has been submitted to show that the proposed changes to the predicate devices do not affect the risk profile of the devices.

5.2 510(k) Summary – Gamma-bsm

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

Contact Person:
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Date Prepared: June 28, 2010

Product Code(s): MQV (21 CFR 888.3045)

Classification Name: Resorbable Calcium Salt Bone Void Filler Device (21 CFR 888.3045)

Device Class: II (21 CFR 888.3045)

Classification Panel: Orthopaedics

FDA Panel Number: 87

Proprietary Name: Gamma-bsm Moldable Bone Substitute Material

Predicate Device(s): Gamma-bsm Moldable Bone Substitute Material (cleared as CaP_3 Bone Void Filler, K033138)
α-BSM (K072636)

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 a 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 bone graft that is a synthetic calcium phosphate, poorly crystalline hydroxyapatite material intended for use in filling bone voids or defects of the skeletal system (i.e. the extremities, posterolateral spine and pelvis) 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 a bone graft substitute that resorbs and is replaced with new bone during the healing process.

Materials: Synthetic calcium phosphate

Performance Data: Regression testing consistent with *Class II Special Controls Guidance Document: Resorbable Calcium Salt Bone Void Filler Device; Guidance for Industry and FDA Staff* (dated June 2, 2003) has been submitted to show that the proposed changes to the predicate devices do not affect the risk profile of the devices.

5.3 510(k) Summary – CarriGen

Submitter:
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Cambridge, MA 02139
Registration No.: 1225112
Owner/Operator No.: 9014709

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Date Prepared: June 28, 2010

Product Code(s): MQV (21 CFR 888.3045)

Classification Name: Resorbable Calcium Salt Bone Void Filler Device (21 CFR 888.3045)

Device Class: II (21 CFR 888.3045)

Classification Panel: Orthopaedics

FDA Panel Number: 87

Proprietary Name: CarriGen Porous Bone Substitute Material

Predicate Device(s): CarriGen Porous Bone Substitute Material (K093447)

Device Description: CarriGen Porous 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 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. CarriGen Porous Carrier Bone Substitute Material is an osteoconductive material that is resorbed and replaced by

natural bone over time.

Intended Use: CarriGen Porous Bone Substitute Material is an injectable, self setting, macro-porous, osteo-conductive, calcium phosphate bone graft substitute material that is intended for use to fill bony voids or gaps of the skeletal system of the extremities, spine (i.e. posterolateral spine), and the pelvis 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. CarriGen is a bone graft substitute that resorbs and is replaced with new bone during the healing process.

Materials: Synthetic calcium phosphate, sodium carboxymethyl cellulose (CMC), sodium carbonate and sodium bicarbonate

Performance Data: Regression testing consistent with *Class II Special Controls Guidance Document: Resorbable Calcium Salt Bone Void Filler Device; Guidance for Industry and FDA Staff* (dated June 2, 2003) has been submitted to show that the proposed changes to the predicate devices do not affect the risk profile of the devices.

5.4 510(k) Summary – EquivaBone

Submitter: ETEX Corporation
38 Sidney Street
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Owner/Operator No.: 9014709

Contact Person: Christopher Klaczyk
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Date Prepared: June 28, 2010

Product Code(s): MQV (21 CFR 888.3045), MBP

Classification Name: Resorbable Calcium Salt Bone Void Filler Device

Device Class: II (21 CFR 888.3045)

Classification Panel: Orthopaedics

FDA Panel Number: 87

Proprietary Name: EquivaBone Osteoinductive Bone Graft Substitute

Predicate Device(s): EquivaBone Osteoinductive Bone Graft Substitute (K090855)

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 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 is a bone graft substitute that combines synthetic calcium phosphate and demineralized bone. It is resorbed and replaced with new bone during the healing process. It is intended for use to fill bony voids or gaps of the skeletal system of the extremities, spine (i.e. posterolateral spine) and pelvis 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.

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

Performance Data: Regression testing consistent with *Class II Special Controls Guidance Document: Resorbable Calcium Salt Bone Void Filler Device; Guidance for Industry and FDA Staff* (dated June 2, 2003) has been submitted to show that the proposed changes to the predicate devices do not affect the risk profile of the devices.

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

ETEX Corporation
c/o Mr. Christopher Klaczyk
Regulatory Affairs Manager
38 Sidney Street
Cambridge, MA 02139

JUL - 1 2010

Re: K101557
Trade/Device Name: Beta-bsm Injectable Bone Graft Substitute Material,
Gamma-bsm Moldable Bone Substitute Material,
CarriGen Porous Bone Substitute Material and
EquivaBone Osteoinductive Bone Graft Substitute
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV, MBP
Dated: June 3, 2010
Received: June 4, 2010

Dear Mr. Klaczyk:

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 application (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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic and
Restorative 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): K101557

Device Name: Beta-bsm Injectable Bone Substitute Material

Indications for Use:

Beta-bsm Injectable Bone Substitute Material is an implantable bone graft that is a synthetic calcium phosphate, poorly crystalline hydroxyapatite material intended for use in filling bone voids or defects of the skeletal system (i.e. the extremities, posterolateral spine and pelvis) 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 a bone graft substitute that resorbs and is replaced with new bone during the healing process.

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 Surgical, Orthopedic,
and Restorative Devices

510(k) Number K101557

4.2 Indications For Use – Gamma-bsm

510(k) Number (if known): K101557

Device Name: Gamma-bsm Moldable Bone Substitute Material

Indications for Use:

Gamma-bsm Moldable Bone Substitute Material is an implantable bone graft that is a synthetic calcium phosphate, poorly crystalline hydroxyapatite material intended for use in filling bone voids or defects of the skeletal system (i.e. the extremities, posterolateral spine and pelvis) 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 a bone graft substitute that resorbs and is replaced with new bone during the healing process.

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 Surgical, Orthopedic, and Restorative Devices

510(k) Number K101557

4.3 **Indications For Use – CarriGen**

510(k) Number (if known): K101557

Device Name: CarriGen Porous Bone Substitute Material

Indications for Use:

CarriGen Porous Bone Substitute Material is an injectable, self setting, macro-porous, osteo-conductive, calcium phosphate bone graft substitute material that is intended for use to fill bony voids or gaps of the skeletal system of the extremities, spine (i.e. posterolateral spine), and the pelvis 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. CarriGen is a bone graft substitute that resorbs and is replaced with new bone during the healing process.

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 Surgical, Orthopedic,
and Restorative Devices

510(k) Number K101557

4.4 Indications For Use – EquivaBone

510(k) Number (if known): K101557

Device Name: EquivaBone Osteoinductive Bone Graft Substitute

Indications for Use:

EquivaBone is a bone graft substitute that combines synthetic calcium phosphate and demineralized bone. It is resorbed and replaced with new bone during the healing process. It is intended for use to fill bony voids or gaps of the skeletal system of the extremities, spine (i.e. posterolateral spine) and pelvis 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.

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 Surgical, Orthopedic,
and Restorative Devices

510(k) Number K101557