510(k) SUMMARY

MAR 17 2011

K103742

Date of Preparation
December 20, 2010

Company
Integra LifeSciences
2 Goodyear
Irvine, CA 92618

Contact
Jenny Fam
Director of Regulatory Affairs
Integra Orthobiologics
949-595-8710

Proprietary Name
Accell Evo3

Common Name
Bone Void Filler

Classification
21 CFR 888.3045; Resorbable calcium salt bone void filler

Product Codes
MQV: Filler, Bone Void, Calcium Compound
MBP: Filler, Bone Void, Osteoinduction (Without Human Growth Factor)

Predicate Devices
The device is substantially equivalent to Integra Accell DBM Family (K061880) and Osteotech Grafton DBM Putty (K051195).

Indications for Use
Accell Evo3 is intended to fill voids and gaps in the skeletal system that are not intrinsic to the stability of the bony structure. The product is indicated for use as a bone graft extender in the spine, extremities and pelvis. Accell Evo3 may also be used as a bone void filler in the posterolateral spine, extremities and pelvis. The voids or gaps may be surgically created defects or the result of traumatic injury to the bone.

Device Description
Accell Evo3 is a moldable putty that contains ground, cortical de-mineralized bone matrix (DBM) in particulate and solubilized forms as well as a poloxamer reverse phase medium for proper handling. The device is packaged in a pre-filled open-bore polycarbonate syringe and terminally sterilized by e-beam radiation. The DBM used to manufacture Accell Evo3 is only obtained from AATB-accredited facilities.

Device Performance
Accell Evo3 is an osteoconductive and osteoinductive bone void filler. The device is resorbed over time and provides a favorable environment that stimulates bone growth and remodeling. Accell Evo3 has been assayed *in vitro* for bone morphogenetic protein-2. The *in vitro* assay has been validated to correlate to an *in vivo* (athymic mouse) osteoinductive assay. It is unknown how osteoinductive potential measured via the *in vitro* or *in vivo* assays will correlate with human clinical performance.

Viral Inactivation
The methods for processing the DBM contained in Accell Evo3 have been evaluated for viral inactivation potential. A panel of model potential human viruses representing various virus types, sizes, shapes and genomes were evaluated. The DBM processing methods have been determined to provide significant viral inactivation for a wide range of potential viruses.

Determination of Substantial Equivalence
Accell Evo3 demonstrated effective bone formation through fusion when tested in the postero-lateral rabbit spine model. Radiographic, histological and biomechanical evidence of the animal study reveal the device's equivalence to autograft controls. The *in vivo* and *in vitro* tests performed on Accell Evo3 demonstrate substantial equivalence in terms of intended use, technological characteristics and performance to its predicate 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

Integra LifeSciences
IsoTis Orthobiologics
% Ms. Jenny Fam
Director of Regulatory Affairs
2 Goodyear
Irvine, California 92672

MAR 17 2011

Re: K103742
Trade/Device Name: Accell Evo3®
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MBP, MQV
Dated: December 20, 2010
Received: December 28, 2010

Dear Ms. Fam:

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.

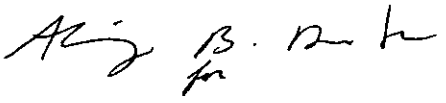
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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

INDICATIONS FOR USE

510(k) Number:

Device Name: Accell Evo3®

Indications for Use:

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Prescription Use ___X____ (Part 21 CFR 801 Sub-part D) AND/OR Over-The-Counter Use _____ (Part 21 CFR 807 Sub-part 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 K103742