## 510(k) Summary: KINEX™ Bioactive

**Company:** Globus Medical Inc.
2560 General Armistead Ave.
Audubon, PA 19403
610-930-1800

**Contact:** Christina Kichula
Group Manager, Regulatory Affairs

AUG 15 2013

**Date Prepared:** February 12, 2013

**Device Name:** KINEX™ Bioactive

**Classification:** Per 21 CFR as follows:
§888.3045 Resorbable Calcium Salt Bone Void Filler
Product Codes: MQV
Regulatory Class: II, Panel Code 87

**Predicate(s):** Vitoss® BA Bioactive BGS K103173 & K994337
NovaBone® Bioactive Bone Graft K080009
InQu® (Bone Void Filler) K103799

**Purpose:**
The purpose of this submission is to request clearance of the KINEX™ Bioactive.

**Device Description:**
KINEX™ Bioactive is a resorbable bone void filler for the repair of bony defects. It is an osteoconductive and osteostimulative material that guides bone regeneration. When KINEX™ is placed in direct contact with host bone, new bone grows in apposition to the surfaces of the implant. As the implant resorbs, bone and other connective tissues grow into the space previously occupied by KINEX™.

KINEX™ implants consist of bioglass (per ASTM F1538), collagen (per ASTM F2212), and hyaluronic acid, and are available in putty, gel, and strip forms to accommodate surgical and anatomical needs.

**Indication for Use:**
KINEX™ Bioactive is intended for use as a bone void filler and autograft extender for voids or gaps that are not intrinsic to the stability of the bony structure. These osseous defects may be surgically created or created from traumatic injury to the bone. KINEX™ Plus Putty and KINEX™ Plus Gel are intended to be gently packed into bony voids or gaps of the skeletal system (i.e., the extremities, pelvis, and spine) and should be combined with bone marrow aspirate. KINEX™ Strip, KINEX™ Plus Strip, KINEX™ Putty and KINEX™ Gel are intended to be gently packed into bony voids or gaps of the skeletal system

(i.e., the extremities, pelvis) and should be combined with bone marrow aspirate. KINEX™ resorbs and is replaced with bone during the healing process.

**Performance Data:**
*In vivo* performance testing (tibia defect model and posterolateral spine fusion model) and biocompatibility testing were conducted in accordance with the "Guidance for Industry and FDA Staff; Class II Special Controls Guidance Document: Resorbable Calcium Salt Bone Void Filler Device," June 2, 2003. Performance data demonstrates substantial equivalence to the predicate device.

**Basis of Substantial Equivalence:**
KINEX™ Bioactive is similar to the predicate devices with respect to technical characteristics, performance, and intended use. The information provided within this premarket notification supports substantial equivalence to the predicate device(s). KINEX™ implants are as safe, as effective, and perform as well as or better than the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

August 15, 2013

Ms. Christina Kichula
Group Manager, Regulatory Affairs
Globus Medical Incorporated
2560 General Armistead Avenue
Audubon, Pennsylvania 19403

Re: K130392
Trade/Device Name: KINEX™ Bioactive
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: June 28, 2013
Received: July 1, 2013

Dear Ms. Kichula:

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 contact 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. 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

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## Indications for Use Statement

510(k) Number: K130392

Device Name: KINEX™ Bioactive

**INDICATIONS:**

KINEX™ Bioactive is intended for use as a bone void filler and autograft extender for voids or gaps that are not intrinsic to the stability of the bony structure. These osseous defects may be surgically created or created from traumatic injury to the bone. KINEX™ Plus Putty and KINEX™ Plus Gel are intended to be gently packed into bony voids or gaps of the skeletal system (i.e., the extremities, pelvis, and spine) and should be combined with bone marrow aspirate. KINEX™ Strip, KINEX™ Plus Strip, KINEX™ Putty and KINEX™ Gel are intended to be gently packed into bony voids or gaps of the skeletal system (i.e., the extremities, pelvis) and should be combined with bone marrow aspirate. KINEX™ resorbs and is replaced with bone during the healing process.

Prescription Use X OR Over-The-Counter Use
(Per 21 CFR §801.109)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Laurence D. Coyne -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K130392