



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Bio2 Technologies, Incorporated
Janet Krevolin, Ph.D.
Chief Technical Officer
12-R Cabot Road
Woburn, Massachusetts 01801

January 12, 2016

Re: K152589

Trade/Device Name: Bio2 CLM•BG Bioactive Scaffold
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV, OIS
Dated: November 30, 2015
Received: December 03, 2015

Dear Dr. Krevolin:

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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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 -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

Indications for Use

510(k) Number (if known)
K152589

Device Name
Bio2 CLM•BG Bioactive Scaffold

Indications for Use (Describe)

The Bio2 CLM•BG Bioactive Scaffold is intended for use as a bone void filler for bony voids or gaps that are not intrinsic to the stability of the bony structure. Bio2 CLM•BG Bioactive Scaffold is indicated to be gently packed into bony voids or gaps of the skeletal system (i.e. extremities and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone.

The product provides a bone void filler that resorbs and is replaced with bone during the healing process.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D) Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Summary of 510(k) safety and effectiveness information upon which the substantial equivalence determination is based:

I. Submitter

Date Prepared: November 20, 2015
Device Submitter: Bio2 Technologies
12-R Cabot Road
Woburn, MA 01801
Phone: 781-721-6309
Contact Person: Janet Krevolin, PhD

II. Device

Device Name: Bio2 CLM•BG Bioactive Scaffold
Common Name: Bone void filler
Classification Name: Resorbable calcium salt bone void filler device (21 CFR 888.3045)
Regulatory Class: II
Product Code: MQV, OIS

III. Predicate Device

Predicate Device: Bio2 Technologies, Bio2 CLM•BG Bioactive Scaffold
K142463
Synthes chronOS K013072
Norian Drillable Bone Void Filler and Norian
Drillable Fast Set Putty K073303

IV. Device Description

The Bio2 Technologies implants are bone void fillers in the shape of cylinders, blocks and wedges. The devices are osteoconductive, bioactive, bone void fillers. The implants are made from a fiber based bioactive glass. The material can be drilled and tapped, and screws can be placed through it. The device structure allows tissue infiltration between the bioactive glass fibers. The fibers then are slowly absorbed and replaced by new bone tissue during the healing process. The cylinders, blocks and wedges are provided sterile and are intended for single use.

V. Indications for Use

The Bio2 CLM•BG Bioactive Scaffold is intended for use as a bone void filler for bony voids or gaps that are not intrinsic to the stability of the bony structure. Bio2 CLM•BG Bioactive

Scaffold is indicated to be gently packed into bony voids or gaps of the skeletal system (i.e. extremities and pelvis). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone.

The product provides a bone void filler that resorbs and is replaced with bone during the healing process.

VI. Comparison of technological characteristics with the predicate device

Bio2 CLM•BG Bioactive Scaffold is an osteoconductive, bioactive bone graft device. The Bio2 CLM•BG Bioactive Scaffold complies with the requirements of ASTM F-1538. *In vitro* testing confirms the formation of a hydroxyapatite layer on the surface of the implant when immersed in simulated body fluid. *In vivo* tests have demonstrated bone formation at each post-implantation time point. In the study critical size defects were filled with Bio2 CLM•BG Bioactive Scaffold and the control material. The rabbit femurs were evaluated at 8 and 16 weeks using x-ray, histology, histomorphometry, SEM and EDX. The Bio2 CLM•BG Bioactive Scaffold was shown to be as safe and effective as the control material.

Bio2 CLM•BG Bioactive Scaffold consists of different size cylinders, blocks and wedges made of degradable and resorbable bioactive glass. When implanted, a kinetic modification of the surface occurs, resulting in the formation of a calcium phosphate layer that is essentially similar in composition and structure to the hydroxyapatite found in bone mineral. This apatite layer provides scaffolding onto which the patient's new bone will grow allowing repair of the defect. The material is radiopaque. Bio2 CLM•BG Bioactive Scaffold implants are intended for single use and are provided sterile to the user. They are completely synthetic and non-collagenous.

VII. Performance Data

Biocompatibility of the device has been established according to blue book memorandum #G95-1 entitled "Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part-1: Evaluation and Testing," *In vitro* bioactivity testing (ISO 23317:2012) shows the material forms a surface apatite layer when submerged in simulated body fluid.

In vivo animal studies show the device achieves bony healing in a critical defect model, confirmed with radiographs, histology and histomorphometry.

VIII. Conclusions

The Bio2 CLM•BG Bioactive Scaffold when compared to the predicates have the same intended use and same indications, technological characteristics, and principals of operation as its predicate device. *In vivo* test data demonstrates that the Bio2 CLM•BG Bioactive Scaffold is as safe and effective as the predicate devices. Thus the Bio2 CLM•BG Bioactive Scaffold is substantially equivalent to the predicate.