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

December 18, 2014

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

Re: K142463
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
Dated: November 6, 2014
Received: November 7, 2014

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" (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 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

Indications for Use

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

510(k) Number *(if known)*
K142463

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

5. 510(k) Summary

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

I. Submitter

Date Prepared: December 4, 2014
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

III. Predicate Device

Predicate Device: NovaBone K101860
Inion BioRestore K090177
OsteoBiologics Inc. PolyGraft K033707
Synthes chronOS K013072

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 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 like the predicate devices is an osteoconductive, bioactive bone graft device. The Bio2 CLM•BG Bioactive Scaffold complies with the requirements of ASTM F-1538. Similar to the predicate devices *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. Similar to the predicate device 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.

Like the predicate devices 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.

Item	*Bio2*	*NovaBone*	*Synthes*
Use	Single use/sterile	Single use/sterile	Single use/sterile
Intended use	Bone void filler	Bone void filler	Bone void filler
Material	Bioactive glass Synthetic and non-collagenous	45S5 Bioglass/ synthetic binder. Synthetic and non-collagenous	β-Tricalcium Phosphate[$Ca_3(PO_4)_2$] Synthetic and non-collagenous
Available Shapes	Cylinders, blocks and wedges	Putty	Cylinders, blocks and wedges
Biocompatible	Yes	Yes	Yes
Form HA in SBF solution	Yes	Yes	-
Radiopaque	Yes	-	Yes
Resorb and form bone in critical size defect, rabbit model	8 and 16 weeks	8 and 16 weeks	-

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 predicate have the same intended use and similar indications, technological characteristics, and principals of operation as its predicate devices. *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 predicates.