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

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

December 30, 2015

Re: K151876
Trade/Device Name: Bio2 Fusion Implant System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HTY
Dated: November 16, 2015
Received: November 17, 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 Parts 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)*

K151876

Device Name

Bio2 Fusion Implant System

Indications for Use *(Describe)*

The Bio2 Fusion Implant System is indicated for fracture fixation, osteotomies, and inter-digital fusion of the fingers, toes and small bones in the presence of appropriate immobilization.

When used in the foot (including hammertoe, claw toe, and mallet toe) patients should use protected weight bearing or heel bearing until fusion or healing has occurred.

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.

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510(k) Summary

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

I. Submitter

Date Prepared:	December 21, 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 Fusion Implant System
Common Name:	Pin, fixation, smooth
Classification Name:	Smooth or threaded metallic bone fixation fastener. 21CFR 888.3040
Regulatory Class:	II
Product Code:	HTY

III. Predicate Device

Predicate Device:	Arthrex, Bio-Pin K050259 Bio2, Bio2 CLM•BG Bioactive Scaffold K142463 Xtremi-T, ReFIX Internal Fixation Pins K043339 Wright, Medical Phalinx K142585

IV. Device Description

The Bio2 Technologies Fusion Implant is a cylindrical shaped implant designed for fracture fixation repair, osteotomy and to fit into the proximal and distal sides of the proximal interphalangeal joints of the foot or hand. The implants are made of bioactive glass material that has been demonstrated to be biocompatible and osteoconductive. The implants are available in multiple diameters, lengths and in a straight and angled configuration. The implants are provided sterile and are intended for single use.

V. Indications for Use

The Bio2 Fusion Implant System is indicated for fracture fixation, osteotomies, and inter-digital fusion of the fingers, toes and small bones in the presence of appropriate immobilization.

When used in the foot (including hammertoe, claw toe, and mallet toe) patients should use protected weight bearing until fusion or healing has occurred.

VI. Comparison of technological characteristics with the predicate device

Bio2 Fusion Implant is a cylindrical shaped implant available in multiple sizes and in straight and angled versions. The implants are dimensionally within the range of the predicate devices. The implants are made of bioactive glass material. The resorbable material has been shown to be biocompatible and osteoconductive.

The material is radiopaque. The Bio2 Fusion Implants are intended for single use and are provided sterile to the user.

VII. Performance Data

Performance testing supports the substantial equivalence of the subject device to the predicate device.

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.

Static and fatigue bending tests and in vitro stability tests were conducted on the subject and predicate devices to demonstrate substantial equivalence.

VIII. Conclusions

The Bio2 Fusion Implant System when compared to the predicate has the same intended use and similar indications, technological characteristics, and principals of operation as its predicate devices. Testing demonstrates that the Bio2 Fusion Implant System is as safe and effective as the predicate device. Thus the Bio2 Fusion Implant System is substantially equivalent to the predicates.