July 28, 2021

Bodycad Laboratories, Inc.
℅ Robert Poggie
President
BioVera Inc.
65 Promenade Saint Louis
Notre-Dame-del-L'Ile-Perrot, Quebec J7V 7P2
Canada

Re: K211646
Trade/Device Name: FINE Osteotomy™
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HRS, HWC, PBF
Dated: May 27, 2021
Received: May 28, 2021

Dear Robert Poggie:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Shumaya Ali, M.P.H.
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211646

Device Name

Fine Osteotomy™

Indications for Use *(Describe)*

Fine Osteotomy™ is a system intended for open- and closed-wedge osteotomies, treatment of bone and joint deformities, fixation of fractures and malalignment caused by injury or disease, such as osteoarthritis, of the distal femur and proximal tibia.

Fine Osteotomy disposable instrumentation is intended to assist in pre-operative planning and/or in guiding the marking of bone and/or guiding of surgical instruments in non-acute, non-joint replacing osteotomies around the knee.

Fine Osteotomy is a patient-specific device.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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."

510(k) SUMMARY – Fine Osteotomy™

In accordance with 21 CFR 807.92 of the Federal Code of Regulations, the following information is a summary of safety and effectiveness of Fine Osteotomy™.

A. SUBMITTERS INFORMATION

Submitter Name:	BioVera, Inc.
Submitter Address:	65 Promenade Saint-Louis, Notre-Dame-De-L'Ile-Perrot, QC, J7V 7P2, CANADA
Contact Person:	Robert A Poggie, PhD
Phone Number:	(514) 901-0796
Fax Number:	(514) 901-0796
Date of Submission:	May 27, 2021

B. DEVICE IDENTIFICATION & MANUFACTURER

Manufacturer Name:	Bodycad Laboratories Inc.
Manufacturer Address:	2035 rue du Haut-Bord, Quebec, Quebec, G1N 4R7, Canada
Registration Number:	3012086398
Contact Name:	Nadine Adia
Title:	Regulatory Affairs Specialist
Device Trade Name:	Fine Osteotomy™
Device Common Name:	Plate, fixation, bone. Screw, fixation, bone.
Classification Name:	Plate, Fixation, Bone; screw, fixation, bone; Single/multiple component metallic bone fixation appliances and accessories; Orthopaedic surgical planning and instruments guide
Classification Codes:	Primary code, HRS. Additional codes, HWC and PBF.
Classification Panel:	Orthopedic
Regulation Numbers:	Primary regulation, 21 CFR 888.3030. Additional regulation, 21 CFR 888.3040.

C. PRIMARY PREDICATE DEVICE

K193614	Bodycad Fine Osteotomy™

D. DEVICE DESCRIPTION

Fine Osteotomy™ is a system for planning and performing osteotomies of the distal femur and proximal tibia, and for stabilizing the bone with bone screws and a patient-specific bone plate that fits the patient's anatomy. Fine Osteotomy™ consists of patient-specific surgical planning and instrument guides designed from images of the patient's bones, a patient-specific bone plate designed from the patient's images, compression and/or locking bone screws, and class 1 reusable manual instruments. The bone plate is a patient-specific, single-use implant; the surgical planning and instrument guides are patient-specific, single-use, and discarded after surgery. Fine Osteotomy™ is offered in three configurations: 1) as a system of patient specific implants and single use instruments for performing osteotomies and implanting hardware to stabilize the resection, 2) as patient specific single use instruments alone for performing osteotomies, and 3) as a patient specific bone plate and screws for stabilizing a bone resection or fracture.

When used as a system, Fine Osteotomy™ enables the surgeon to perform an osteotomy and stabilize the bone around the knee that matches the pre-surgical plan using the patient-specific cutting guides and bone plate. When the planning guides and resection instruments are used alone, Fine Osteotomy™ enables the surgeon to perform an osteotomy around the knee that matches the pre-surgical plan using the patient-specific cutting guides designed from the patient's CT images. When the bone plate and screws are used alone, Fine Osteotomy™ enables the surgeon to stabilize fractured or resected bone per the pre-surgical plan using the patient's CT images in design of the Bodycad plate and use of the bone models intra operatively to guide placement of the implants and alignment of bone. The Fine Osteotomy System is provided clean, not sterile to the user.

The purpose of this 510(k) is to notify the FDA of changes to the software, implants, single use instruments, packaging, and labeling of the Fine Osteotomy System cleared in K193614.

Materials: Wrought Titanium-6Aluminum-4Vanadium ELI Alloy (Ti6Al4V ELI; ASTM F136-13) for the bone plates and screws, ADM Nylon-12 for patient specific resection guides and models.

E. INTENDED USE

Fine Osteotomy™ is a system intended for open- and closed-wedge osteotomies, treatment of bone and joint deformities, fixation of fractures and malalignment caused by injury or disease, such as osteoarthritis, of the distal femur and proximal tibia.

Fine Osteotomy disposable instrumentation is intended to assist in pre-operative planning and/or in guiding the marking of bone and/or guiding of surgical instruments in non-acute, non-joint replacing osteotomies around the knee.

Fine Osteotomy is a patient-specific device.

F. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The subject device, Bodycad's Fine Osteotomy™ System, has the same intended use and technological features and similar indications for use as the primary predicate device which is Bodycad's Fine Osteotomy System cleared in K193614. The following points compare the technological features of the subject and predicate devices.

- The indications for use for the subject device and predicate devices are similar to the indications for use for the Bodycad predicate device; the subject and predicate devices are intended to facilitate osteotomy about the knee.
- The single use disposable instruments for the subject device have the same intended and indicated uses as the primary predicate device.
- The line extension of T20 compatible bone screws for the subject device are similar in geometry and length range as the primary predicate device. The subject device T20 bone screws are designed to interface with the subject device Bodycad patient specific bone plates in the same manner as the T15 bone screws and patient specific bone plate for the primary predicate device. Torsional strength and fixation testing demonstrated substantial equivalence of the Bodycad T15 and T20 screws because there is no difference in the design of the thread form and minor and major diameters of the Bodycad T15 and T20 bone screws.
- The design features, geometry, and size range of the patient specific bone plates are the same for the subject and primary predicate devices. The minimum bending strength of the bone plates remains the same for the subject devices relative to that cleared for the primary predicate device because: (1) The minimum cross-section modulus and bounding-box for the bone plates are the same for the subject and primary predicate devices, and (2) there was no change in the minimum distances between screw holes of the bone plate and the location of the bone fracture or osteotomy. Engineering analysis indicated no new worst case was created by the updated design of the bone plate to accommodate the head of the T20 compatible bone screws.
- Verification and validation activities demonstrated that the Bodycad software used to design the subject device patient specific guides and implants is substantially equivalent to the Bodycad software used to design the primary predicate devices.
- The subject and primary predicate devices are both provided clean, not sterile to the user; the original cleaning and sterility validation were applicable to the subject device because no new worst case was created by the updates to the Fine Osteotomy System.

G. PERFORMANCE DATA

The changes to the software and implant and instrument design were analyzed, tested, and validated as required for the Bodycad Fine Osteotomy™ System using Bodycad standard operating procedures and ASTM and ISO consensus standards. The following list summarizes the performance testing and validation and verification activities.

- Mechanical performance testing of the T20 compatible bone screws with comparison to the primary predicate T15 bone screws per ASTM F543 and FDA Guidance Document "Orthopedic Non-Spinal Metallic Bone Screws and Washers, Performance Criteria for Safety and Performance Based Pathway". The results of this testing showed no significant

difference in torsional strength and fixation into simulated bone between the subject T20 and the primary predicate T15 bone screws.

- Engineering analysis of the subject bone plate device relative to the minimum section modulus / design of the primary predicate bone plate demonstrated that no new worst case was created relative to the least strong predicate bone plate.
- The Bodycad software for Fine Osteotomy was re-validated per FDA guidance documents.
- Biocompatibility of implants and instruments were evaluated per ISO 10993-1. The original assessment of biocompatibility of the primary predicate device was adopted for the subject device because no new materials, manufacturing processes, or worst-case device was created by the line extension of T20 screws and minor design updates.
- The original cleaning and sterility validation of the implant and disposable instrument kit and the reusable instrument kit were applicable to the subject device because no new worst cases were created by the updates to the Fine Osteotomy System.
- Cleaning and sterilization was validated to a SAL of 10^{-6} by Nelson Labs for a new screw tray cady and bone screws per the partial cycle validation approach outlined in ANSI/AAMI/ISO 17665-1:2006/(R)2013, Annex D and the validation approach outlined in ANSI/ AAMI/ISO 14937:2009/(R)2013, Annex D (Approach 3).

The results of performance testing demonstrated substantial equivalence for Fine Osteotomy subject devices relative to the predicate and reference devices.

H. CONCLUSION

Bodycad's Fine Osteotomy™ System is substantially equivalent to the identified primary predicate device based on similarities in indications for use, materials, design, size, technological characteristics, and performance data presented in this 510(k) notification.