March 25, 2020

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

Re: K193614
Trade/Device Name: FINE Osteotomy around the knee
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: December 20, 2019
Received: December 26, 2019

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K193614

Device Name

Fine Osteotomy™

Indications for Use *(Describe)*

Fine Osteotomy is a system intended for 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.

Specifically,
- The Fine Osteotomy tibial plates are indicated for open- and closed-wedge osteotomies of the medial proximal tibia, treatment of bone and joint deformities, fractures, non-unions, and malalignment caused by injury or disease, such as osteoarthritis, of the proximal tibia.
- The Fine Osteotomy femoral plates are indicated for open- and closed wedge osteotomies of the medial and lateral distal femur, treatment of bone and joint deformities, fractures, non-unions, and malalignment caused by injury or disease, such as osteoarthritis, of the distal femur.
- Fine Osteotomy instrument guides are 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.

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K193614

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, Quebec, J7V 7P2, CANADA
Contact Person:	Robert A Poggie, PhD
Phone Number:	(514) 901-0796
Fax Number:	(514) 901-0796
Date of Submission:	December 20, 2019

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:	Guy Sevigny
Title:	Director, Regulatory Affairs
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 Code:	HRS, HWC, and PBF – Class II
Classification Panel:	Orthopedic
Regulation Number:	21 CFR section 888.3030

C1. PREDICATE DEVICES

Primary Predicate Device	
K081353	SYNTHES TOMOFIX MEDIAL DISTAL FEMUR PLATES
Predicate Devices	
K023941	SYNTHES TOMOFIX Osteotomy System
K183011	Additive Orthopaedics Patient Specific 3D Locking Lattice Plates
K132290	MATERIALISE - Surgicase orthopaedics system, surgicase connect, surgicase guides

C2. REFERENCE DEVICES

K014155	Arthrex - Opening Wedge Osteotomy System
K191996	BC Reflex Uni

D. DEVICE DESCRIPTION

Fine Osteotomy™ for the knee 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 designed to fit the patient's anatomy. Fine Osteotomy™ consists of patient-specific surgical planning and instrument guides designed from long-standing x-ray and computed tomography (CT) images of the patient's bones, a patient-specific bone plate designed from the CT images, compression and/or locking bone screws, and manual reusable instruments. The bone plate is a patient-specific, single-use implant; the patient-specific surgical planning and instrument guides are 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 the osteotomy and implanting hardware to stabilize the resection, 2) as patient specific single use instrumentation for performing an osteotomy alone, and 3) as 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 via the patient-specific cutting guides and bone plate designed from the patient's CT images. When the planning guides and resection instruments are used alone, Fine Osteotomy™ enables the surgeon to perform an osteotomy the bone around the knee that matches the pre-surgical plan via 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.

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 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.

Specifically,
- The Fine Osteotomy™ tibial plates are indicated for open- and closed-wedge osteotomies of the medial proximal tibia, treatment of bone and joint deformities, fractures, non-unions, and malalignment caused by injury or disease, such as osteoarthritis, of the proximal tibia.
- The Fine Osteotomy™ femoral plates are indicated for open- and closed wedge osteotomies of the medial and lateral distal femur, treatment of bone and joint deformities, fractures, non-unions, and malalignment caused by injury or disease, such as osteoarthritis, of the distal femur.

- Fine Osteotomy™ instrument guides are 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

Fine Osteotomy™ has the same intended use and technological features as the predicate devices K023941, K081353, K183011, and K132290, and reference device K014155. Design features and clinical indications that are common to the subject, predicate, and reference devices include locking and compression cortical bone screws, compression cancellous bone screws, opening wedge for mechanical support of the bone at the osteotomy site, two or more holes superior and inferior to the osteotomy or fracture site, minimum strength for supporting and stabilizing bone during the healing period, patient-specific bone resection guides and models to assist and guide bone resection and for guiding implant placement, patient specific bone plates, and resection instruments and implants for opening and closing wedge osteotomies in the tibia and femur. Fine Osteotomy™ implants, single use instruments, and reusable instruments are provided to the user clean, and not sterile. Bodycad has validated cleaning and sterilization of Fine Osteotomy devices. Comparison of the design features with those of the predicate devices demonstrates substantial equivalence for the subject, predicate, and reference devices.

G. PERFORMANCE DATA

Pre-clinical performance testing was performed for the Bodycad Fine Osteotomy™ System per ASTM and ISO consensus standards, the scientific literature, and pre-submission Q190553. The following list summarizes the performance testing and validation and verification activities.

- Mechanical performance testing, design, and criteria for acceptance per ASTM F543, ISO 5835, ISO 10664, and FDA Guidance Document “Orthopedic Non-Spinal Metallic Bone Screws and Washers, Performance Criteria for Safety and Performance Based Pathway”.
- Mechanical bending strength characteristics of worst case, least strong subject plate device relative to minimum section modulus / design using ASTM F382.
- Evaluation of biomechanical characteristics of subject devices in simulated HTO model, with comparison to predicate and reference devices.
- Cadaver simulation of use of the Fine Osteotomy system and measurement of accuracy of correction and position of implants relative to surgical plan, conventional technique, and reference devices.
- Validation and verification of software per FDA guidance documents.
- Evaluation of biocompatibility of implants and instruments per ISO 10993-1.
- Validation of reusable instrument reprocessing parameters for cleaning and sterilization, and for dimensional stability and particulate debris of the ADM Nylon-12 resection guides.

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 predicate and reference devices based on similarities in indications for use, materials, design, size, technological characteristics, and performance data presented in this 510(k) notification. Fine Osteotomy™ subject components share the same intended uses and are substantially equivalent to the predicate and reference devices identified in this 510(k) notification.