September 5, 2024

Bodycad Laboratories Inc.
Nadine Adia
Regulatory Affairs and Quality Director
2035 rue du Haut-Bord
Quebec, G1N4 R7
Canada

Re: K241356
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: August 12, 2024
Received: August 12, 2024

Dear Nadine Adia:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Christopher Ferreira -S

Christopher Ferreira, MS
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241356

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.

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510(k) #: K241356

510(k) Summary

Prepared on: 2024-08-09

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Bodycad Laboratories Inc.
Applicant Address	2035 rue du Haut-Bord Quebec G1N4 R7 Canada
Applicant Contact Telephone	4185271388
Applicant Contact	Mrs. ADIA Nadine
Applicant Contact Email	nadia@bodycad.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Fine Osteotomy™
Common Name	Single/multiple component metallic bone fixation appliances and accessories
Classification Name	Plate, Fixation, Bone
Regulation Number	888.3030
Product Code(s)	HRS, HWC, PBF

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K141796	DePuy Synthes TOMOFIX Osteotomy System	HRS
K240703	Fine Osteotomy™	HRS

Device Description Summary

21 CFR 807.92(a)(4)

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.

This 510(k) submission is intended to notify the FDA of the enhancements to the mechanical locking system, the addition of new screw lengths, and option to use a new in-house software for planning and cutting guide design in the Fine Osteotomy System, previously cleared in K240703.

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

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

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.

Indications for Use Comparison

21 CFR 807.92(a)(5)

No changes have been made to the Indications for Use statement for Fine Osteotomy™ in this submission.

Technological Comparison

21 CFR 807.92(a)(6)

Fine Osteotomy™ retains the same intended use and technological characteristics as the predicate devices K141796 , and reference device K240703. This includes common design features and clinical indications such as locking and compression cortical bone screws, compression cancellous bone screws, and an opening wedge for mechanical support at the osteotomy site. Additionally, the devices share features like two or more holes positioned superior and inferior to the osteotomy or fracture site, minimum strength requirements for supporting and stabilizing bone during healing, and patient-specific bone resection guides and models to assist in bone resection and guide implant placement. Moreover, patient-specific bone plates, resection instruments, and implants are utilized for both opening and closing wedge osteotomies in the tibia and femur.
In this submission, we have enhanced the mechanical locking system to improve stability and reliability, ensuring a more secure and durable fixation of bone screws that aligns with the locking features of the predicate devices. We have also introduced additional screw lengths (75mm, 80mm, 85mm, and 90mm) exclusively for the locking configuration, providing surgeons additional options for optimal fit and stabilization, and maintaining the principle of adjustable mechanical support found in the predicate devices. Furthermore, the introduction of Application Creator into the Fine Osteotomy medical device manufacturing process enables the creation of patient-specific cutting guides by converting medical imaging data into 3D models manually. This integration complements existing design features while advancing the capability of the system to provide personalized surgical solutions based on individual patient anatomy.
Fine Osteotomy™ implants, single-use instruments, and reusable instruments are supplied clean but non-sterile, consistent with the predicate and reference devices. The comparison of design features with those of the predicate devices supports the claim of substantial equivalence for the subject, predicate, and reference devices, confirming that the modifications do not alter the intended use or safety profile of the device.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Non-Clinical Tests:
Mechanical Testing
- Torsional and Pull-Out Strength: Tests conducted on the locking screws and bone plates demonstrated mechanical strength, exceeding the performance of predicate devices.
- Bending Resistance: The device was subjected to static and dynamic cantilever bending tests, which confirmed its enhanced structural integrity .
- Push-Out Test: Measure the axial force required to dislodge locking screws from the bone plates, crucial for osteotomy repair stability.

The mechanical testing, including torsional, pull-out, and push-out tests, alongside software validation demonstrates that the Fine Osteotomy™ system meets all necessary performance and safety standards.