August 21, 2025

Bodycad Laboratories Inc.
Nadine Adia
Regulatory Affairs and Quality Director
2035 rue du Haut-Bord
Quebec, G1N 4R7
Canada

Re: K250923
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: June 5, 2025
Received: June 5, 2025

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, M.S.
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K250923

Please provide the device trade name(s).

Fine Osteotomy™

Please provide your Indications for Use below.

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.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) #: K250923

510(k) Summary

Prepared on: 2025-08-04

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Bodycad Laboratories Inc.
Applicant Address	2035 rue du Haut-Bord Quebec G1N4R7 Canada
Applicant Contact Telephone	4186559250
Applicant Contact	Mrs. Nadine Adia
Applicant Contact Email	nadia@bodycad.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Fine Oseotomy
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
K241356	Fine Osteotomy™	HRS

Device Description Summary

21 CFR 807.92(a)(4)

The Fine Osteotomy™ System is a patient-specific orthopedic device designed to assist surgeons in planning and performing precise osteotomies around the knee. It utilizes patient imaging data to create 3D anatomical models used for the design of cutting guides and fixation implants tailored to the individual anatomy.The system includes single-use cutting guides manufactured from PA12 polymer and fixation components made of titanium alloy (Ti-6Al-4V ELI). The implants are designed to support stable bone fixation following the osteotomy. The device operates without an energy source and relies on mechanical alignment and rigid fixation principles.Minor refinements have been incorporated to improve compatibility with surgical planning and instrument design, without affecting the intended use or fundamental function of the system.The device is supplied non-sterile and includes a combination of patient-specific and reusable components.

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)

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.

Technological Comparison 21 CFR 807.92(a)(6)

The Fine Osteotomy™ System retains the same technological characteristics as its previously cleared predicate devices, including overall design, materials, intended use, and operating principles. The system remains a patient-specific mechanical fixation solution without an energy source. Minor updates have been implemented to expand the range of compatible components, align documentation with existing validated designs, support usability through a software update, and enhance packaging and fixation options. These changes do not alter the fundamental performance or safety of the system. All modifications have been verified and validated to ensure continued conformity with the intended use and predicate performance.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Non-clinical testing was performed to support the proposed modifications to the Fine Osteotomy™ System. The testing included verification of dimensional and functional attributes of components, packaging evaluation, and software verification and validation. All tests confirmed that the device meets applicable requirements and continues to perform as intended. No clinical testing was necessary, as the modifications do not alter the intended use, safety, or effectiveness of the device. The results support the conclusion that the device is substantially equivalent to the predicate.