



October 28, 2025

Bodycad Laboratories Inc.
Nadine Adia
Regulatory Affairs and Quality Director
2035 rue du Haut-Bord
Quebec, G1N4R7
Canada

Re: K253300

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: September 29, 2025

Received: September 29, 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.

K253300

?

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)

?

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	+14186229250
Applicant Contact	Mrs. Nadine Adia
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
K250923	Fine Osteotomy™	HRS

Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

The Fine Osteotomy™ System is an orthopedic fixation system used to stabilize bone fragments during corrective osteotomies of the distal femur or proximal tibia. The system supports proper alignment and promotes bone healing through rigid internal fixation. The system includes: Metallic bone plates (femoral and tibial) in open- and closed-wedge configurations. Bone screws compatible with the plates. Reusable surgical instruments for positioning and fixation. The plates and screws are made of titanium alloy Ti-6Al-4V ELI, a biocompatible material widely used in orthopedic implants.

The closed-wedge plates now include an oblong hole to enable controlled axial compression at the osteotomy site. An additional glass-bead-blasted surface finish for the plates has been validated to meet the same smoothness requirement as the existing polished finish. The plates are low-profile, anatomically contoured, and fixed with compatible self-tapping screws. The device functions as a load-sharing internal fixation system to maintain alignment during healing.

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 subject Fine Osteotomy™ System has the same fundamental technological characteristics as the predicate device (K250923). Both systems share the same principle of operation (rigid internal fixation of the osteotomy site), intended use (stabilization of bone fragments in planned osteotomies of the distal femur or proximal tibia), design concept (anatomically contoured metallic plates fixed with compatible screws), energy source (mechanical fixation only, no electrical components), and material (titanium alloy Ti-6Al-4V ELI per ASTM F136).

The only changes introduced are:

- The addition of an oblong hole in the closed-wedge plates to allow controlled axial compression at the osteotomy site.
- The addition of a glass-bead-blasted surface finish for the plates.

These modifications do not change the principle of operation, materials, or overall device function and do not raise new questions of safety or effectiveness compared to the predicate device.

Non-Clinical and/or Clinical Tests Summary & Conclusions

[21 CFR 807.92\(b\)](#)

Verification and Validation Activities:

- Mechanical engineering analysis confirmed that the addition of the oblong hole in the closed-wedge plates does not introduce new risks or worst-case scenarios and that the device continues to meet performance requirements.
- Surface finish evaluation confirmed that the new glass-bead-blasted finish meets smoothness requirements and does not introduce new risks to safety or performance.

All results met predefined acceptance criteria. No new clinical data were required, as the changes do not affect the intended use or raise new questions of safety or effectiveness. The device remains safe, effective, and substantially equivalent to the predicate device.