October 21, 2025

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

Re: K250394
Trade/Device Name: Fine TTO™
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: PBF, HWC
Dated: September 18, 2025
Received: September 18, 2025

Dear Ms. 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,

Shumaya Ali -S

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

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.	K250394

Please provide the device trade name(s).

Fine TTO™

Please provide your Indications for Use below.

Fine TTO™ is a patient-specific system intended for tibial tuberosity osteotomies (TTO) in skeletally mature patients.
The device is intended to assist in pre-operative planning and in guiding surgical instruments during the procedure, and should be used only when the anatomical landmarks required for planning can be clearly identified on the patient's radiographic images.

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) #: K250394

510(k) Summary

Prepared on: 2025-10-16

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 TTO™
Common Name	Single/multiple component metallic bone fixation appliances and accessories
Classification Name	Orthopaedic Surgical Planning And Instrument Guides
Regulation Number	888.3030
Product Code(s)	PBF, HWC

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K241356	Fine Osteotomy	PBF

Device Description Summary

21 CFR 807.92(a)(4)

The Fine TTO™ system is designed specifically for tibial tuberosity osteotomies to adjust the alignment and positioning of the tibia for improved knee mechanics in skeletally mature patients. This system uses advanced imaging techniques, such as X-rays and CT scans, to create precise, patient-specific cutting guides. These guides assist surgeons in accurately cutting and repositioning the tibial tuberosity, ensuring the adjustments closely match the pre-surgical planning.

The primary function of Fine TTO™ is to facilitate precise bone cuts and ensure optimal placement according to the surgical plan, which is tailored to the patient's unique anatomy. The scientific concept behind Fine TTO™ relies on biomechanical principles of bone alignment and load distribution in the knee joint, aiming to restore the natural mechanics.

Device design and materials:

• Cutting Guides: Made from medical-grade polymers that are biocompatible and capable of providing the necessary rigidity and precision for bone cutting operations. These guides are designed for single use to ensure sterility and accuracy.

• Implants (Screws): Made from titanium alloy (Ti-6Al-4V ELI), known for its strength, biocompatibility. This material is standard in orthopedic applications and helps in the fixation process post-osteotomy.

Physical and performance characteristics:

• The system's design ensures that the cutting guides fit precisely to the patient's bone structure, reducing the risk of intraoperative errors and improving the predictability of the surgical outcomes.

• The titanium screws used in the system provide strong, durable fixation that can withstand the mechanical forces exerted by the body weight and movement, supporting proper bone healing.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Fine TTO™ is a patient-specific system intended for tibial tuberosity osteotomies (TTO) in skeletally mature patients.

The device is intended to assist in pre-operative planning and in guiding surgical instruments during the procedure, and should be used

only when the anatomical landmarks required for planning can be clearly identified on the patient's radiographic images.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The indications for use of Fine TTO™ are closely aligned with those of its predicate device, Fine Osteotomy, focusing on osteotomy procedures around the knee. While Fine Osteotomy addresses broader osteotomies of the femur and tibia, Fine TTO™ specifically targets tibial tuberosity adjustments. This specialization does not constitute a new intended use but rather a more focused application of the existing technology within the same anatomical region. Both devices facilitate precise surgical modifications to correct bone deformities and misalignments, leveraging patient-specific surgical planning and implantation techniques.

Technological Comparison 21 CFR 807.92(a)(6)

Fine TTO™ shares several fundamental technological characteristics with its predicate device, Fine Osteotomy, which validates its comparability in terms of design principles, material composition, and operation methodology. Both devices utilize Ti-6Al4V ELI, a biocompatible titanium alloy, for their implant screws, adhering to standards ASTM F136 and ISO 5832-3, ensuring high compatibility and resilience.Both systems employ patient-specific cutting guides, crafted from detailed patient imaging data (X-ray and CT scans), which allows for precise bone cutting and adjustments tailored to individual anatomical structures. This patient-specific approach underlies the principle of operation for both devices, emphasizing precision in surgical planning and execution.However, Fine TTO™ differs slightly in its implementation: it is specifically designed for tibial tuberosity osteotomies and does not include a bone plate, which is a component of the Fine Osteotomy system. Instead, Fine TTO™ relies exclusively on screw fixation to maintain bone positioning and stability post-surgery. This distinction does not alter the fundamental technology or its application but rather adapts it to more specific surgical needs within the same anatomical region.Despite these differences, the core technology of patient-specific guides and the material used for the screws remain consistent, ensuring that Fine TTO™ maintains similar performance characteristics, safety profiles, and intended surgical outcomes as the Fine Osteotomy. Thus, the technological characteristics of Fine TTO™ align closely with those of its predicate, providing the same high level of precision and adaptability without introducing new or untested technology.

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

The Fine TTO"' system was evaluated through the following non-clinical tests:
- Cadaveric accuracy testing
- Debris assessment
- Dimensional stability testing post reprocessing and transport
- Mechanical testing of screws per ASTM F543
- Intra- and inter-designer variability testing

All tests met their acceptance criteria. The results confirm that the Fine TTO™ system is substantially equivalent to the predicate.