October 29, 2025

Meduloc, LLC
Benjamin Arnold
CEO
2010 Jimmy Durante Blvd
Suite 200
Del Mar, California 92014

Re: K250316
Trade/Device Name: Meduloc Intramedullary Fracture Fixation (IFF) System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: JDW, HWC, HTY
Dated: February 1, 2025
Received: February 4, 2025

Dear Mr. Arnold:

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

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)*

K250316

Device Name

Meduloc Intramedullary Fracture Fixation (IFF) System

Indications for Use *(Describe)*

The Meduloc Intramedullary Fracture Fixation (IFF) System is intended for use in the fixation of long bone fractures in both adult and pediatric applications.

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.

510(k) Summary

SUBMITTER:

Company Name:	Meduloc, LLC
Address:	2010 Jimmy Durante Blvd, Suite 200 Del Mar, CA 92014
Telephone:	607.351.6131

CONTACT PERSON:	Benjamin Arnold
DATE PREPARED:	October 22, 2025
TRADE NAME:	Meduloc Intramedullary Fracture Fixation (IFF) System
COMMON NAME:	Screw, Fixation Bone
CLASSIFICATION NAME:	Smooth or threaded metallic bone fixation fastener (21 CFR 888.3040)
REGULATORY CLASS:	II
PRODUCT CODE:	JDW, HWC, HTY

SUBSTANTIAL EQUIVALENCE:
The Meduloc IFF System is substantially equivalent to the primary predicate device in all facets including function, design, performance, material, and intended use.

Primary Predicate Device:	Komet Medical Kirschner Wires, Steinmann Pins and Guide Pins and Screws (K131264)

DEVICE DESCRIPTION:
The Meduloc Intramedullary Fracture Fixation (IFF) System is intended to treat small, long-bone fractures. It consists of three implants: Intramedullary Wire, Bone Anchor, and Locking Screw. The implants are provided in various sizes to accommodate varying patient anatomy. The system also contains a set of ancillary instruments. All elements of the System are Gamma sterilized and provided sterile-packed and are single-use.

MATERIALS:
The Intramedullary Wire implant is made from nitinol. The Bone Anchor and Locking Screw are made from Ti-6Al-4V.

INDICATIONS FOR USE:
The Meduloc Intramedullary Fracture Fixation (IFF) System is intended for use in the fixation of long bone fractures in both adult and pediatric applications.

TECHNOLOGICAL CHARACTERISTICS:
The Meduloc IFF System implant components are made from similar materials and have equivalent design philosophy, sizing, configurations, fixation methods, sterilization and packaging, and surgical

approach to the predicate device. Any differences between the Meduloc IFF System and the predicate are considered minor and do not raise questions concerning safety or effectiveness.

PERFORMANCE TESTING:
The following bench testing was performed on the Meduloc IFF System**:**

- Intramedullary Wire Static Torsion
- Intramedullary Wire Static Bending
- Intramedullary Wire Dynamic Bending
- Bone Anchor Axial Pullout
- Bone Anchor Driving Torque
- Corrosion Susceptibility
- Nikel Ion Release Testing
- Static Pullout and Dynamic Cantilever Testing
- Custom Static Compression Testing
- Af Temperature Testing
- Packaging Validation
- Biocompatibility Adoption Rationale
- Sterilization

In summary, rationales and mechanical testing of the Meduloc IFF System indicated there are no new risks and demonstrated substantial equivalence in performance compared to a legally marketed predicate.

CONCLUSIONS:
The Meduloc IFF System is substantially equivalent to legally marketed predicates based on indications for use, technological characteristics, performance testing, and comparison to predicate devices.