March 4, 2026

Satori Orthopaedics, Inc.
% Haylie Fast
Consultant
Fast Consulting Services, LLC
6357 Westview Circle
Parker, Colorado 80134

Re: K252025
Trade/Device Name: Active Intramedullary (AIM) Tibial Nail System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: January 30, 2026
Received: February 2, 2026

Dear Haylie Fast:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the Medical Device File (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 Management System Regulation (QMSR) (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,

FARZANA SHARMIN -S

Farzana Sharmin, PhD
Assistant Director
DHT6A: Division of Joint Arthroplasty 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)*

K252025

Device Name

Active Intramedullary (AIM) Tibial Nail System

Indications for Use *(Describe)*

The Active Intramedullary (AIM) Tibial Nail System is indicated for the following:

- Open or closed fractures of the tibial shaft
- Proximal or distal tibial shaft fractures
- Tibial shaft fractures including transverse, short oblique, long oblique, and comminuted fracture patterns
- Tibial non-unions and malunions
- Pathologic and/or impending fractures

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

510(k) Number:	K252025
Date Prepared:	March 3, 2026

Contact Details:

Applicant Name	Satori Orthopaedics, Inc.
Applicant Address	3101 E. Shea Blvd Suite 122 Phoenix AZ 85028 United States
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Correspondent Contact	Mrs. Haylie Fast
Correspondent Contact Email	haylie.fast@fcservices-llc.com

Device Name:

Device Trade Name	Active Intramedullary (AIM) Tibial Nail System
Common Name	Rod, Fixation, Intramedullary and Accessories
Classification Name	21 CFR 888.3020, Intramedullary Fixation Rod
Regulation Number	888.3020
Product Code(s)	HSB

Legally Marketed Predicate Devices:

Primary Predicate:	K170972, Apex Tibial Nailing System, HSB
Additional Predicates:	K083459, NovaLign Intramedullary Fixation System, HSB K113828, MedShape Solutions DynaNail Ankle Arthrodesis Nail, HSB K082770, Zimmer Natural Nail Tibial Nail, HSB K202099, Galileo™ Trochanteric Nail System, HSB

Device Description:

The AIM Tibial Nail System is a tibial intramedullary fixation rod designed to be implanted proximally and distally to a fracture line. The system consists of the Intramedullary (IM) Nail and Interlocking Screws. The IM Nail is made from titanium alloy and includes an internal compression spring for compression force/axial movement.

Intended Use/Indications for Use:

The Active Intramedullary (AIM) Tibial Nail System is indicated for the following:

- Open or closed fractures of the tibial shaft
- Proximal or distal tibial shaft fractures
- Tibial shaft fractures including transverse, short oblique, long oblique, and comminuted fracture patterns
- Tibial non-unions and malunions
- Pathologic and/or impending fractures

Indications for Use Comparison:

The AIM Tibial Nail System is substantially equivalent to the predicate devices with respect to intended use and indications.

Technological Comparison:

The AIM Tibial Nail System possesses the same intended use and technological characteristics as the predicate devices. Additionally, the preclinical testing support the substantial equivalence of the AIM Tibial Nail System to the predicates. Therefore, the AIM Tibial Nail System is substantially equivalent for its intended use.

Non-Clinical and/or Clinical Tests Summary & Conclusions:

Nonclinical testing included the following:

1. Static and dynamic mechanical testing of the nail per ASTM F1264
2. Compression fatigue testing of the spring
3. Compression (fatigue) testing of the nail, followed by:
    a. Corrosion Evaluation
    b. Particulate Debris Evaluation
4. Static and dynamic mechanical testing of the screws per ASTM F543
5. Engineering Justification of Interlocking Screws
6. Dynamic mechanical testing of the screw per ASTM F1264

Clinical testing is not applicable to demonstrate substantial equivalence.

These results support the substantial equivalence of the AIM tibial nail to the predicate and support adequate device performance when used as intended.