October 17, 2025

Citieffe s.r.l.
Federica Giovetti
Quality and Regulatory Manager
Via Armaroli 21
Calderara di Reno, BO 40012
Italy

Re: K250197
Trade/Device Name: Estremo Fibular Nail
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: September 17, 2025
Received: September 17, 2025

Dear Federica Giovetti:

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,

Joseph P. Russell -S

Digitally signed by Joseph P. Russell -S
Date: 2025.10.17 09:04:10 -04'00'

for: 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)*

K250197

Device Name

Estremo Fibular Nail

Indications for Use *(Describe)*

Estremo Fibular Nail is intended for use in the fixation of fibula fractures and osteotomies.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) #: K250197

510(k) Summary

Prepared on: 2025-10-15

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Citieffe s.r.l.
Applicant Address	Via Armaroli 21, Calderara di Reno BO 40012 - Italy
Applicant Contact Telephone	00390510543232
Applicant Contact	Mrs. Federica Giovetti
Applicant Contact Email	giovetti@citieffe.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Estremo Fibular Nail
Common Name	Rod, Fixation, Intramedullary And Accessories
Classification Name	Intramedullary fixation rod
Regulation Number	888.3020
Product Code(s)	HSB

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K173656	Arthrex FibuLock Nail	HSB
K192710	The Simple Locking Intramedullary (Slim) System	HSB

Device Description Summary

21 CFR 807.92(a)(4)

Estremo Fibular Nail includes all implants and instruments required for the fixation of fibula fractures and osteotomies. Estremo Fibular Nail includes the nails, screws, end caps and related instruments. Estremo Fibular Nail Nail differs from traditional nails or rods as it utilizes a "Diapason wings deployment" mechanism at the proximal end of the rod to allow for proximal fixation with a screw. The implants are composed of 316L stainless steel per ASTM F138 and are provided sterile.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Estremo Fibular Nail is intended for use in the fixation of fibula fractures and osteotomies.

Indications for Use Comparison

21 CFR 807.92(a)(5)

Estremo Fibular Nail has the same indications for use of the primary predicate device Arthrex FibuLock Nail (K173656)

Technological Comparison

21 CFR 807.92(a)(6)

Estremo Fibular Nail is similar to the legally marketed primary predicate device with respect to intended use and design. The technological characteristics between the subject device, primary predicate and additional predicate are similar.
The primary predicate device and the subject device are both angled nails and both devices allow the use of one or two syndesmotic screws. Moreover, both have proximal locking mechanism and distal locking with screws. However, the lengths of the subject device nails are not completely within the range of the primary predicate; therefore, an additional predicate that features a wider range of lengths has been introduced for an exhaustive mechanical comparison.
Estremo Fibular Nail differs from traditional nails or rods as it utilizes a "Diapason wings deployment" mechanism at the proximal end of the rod to allow for proximal fixation with a screw.

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

All necessary testing has been performed on representative Estremo Fibular Nail components (nails and screws) to assure substantial equivalence to its predicate and demonstrate the subject device performs as intended. All testing was performed on finished devices.
The Estremo Fibular Nail has been tested in accordance with ASTM F1264, the screws have been tested in accordance with ASTM F543.
A list of the tests carried for this application can be found below:

- Static torsion mechanical testing of IMFD
- Static torsion mechanical testing of IMFD Locking Screws
- Driving torque mechanical testing of IMFD Locking Screws
- Pull-out mechanical testing of IMFD Locking Screws
- Self-tapping performance mechanical testing of IMFD Locking Screws
- Bending Fatigue mechanical testing of IMFD Locking Screws
- Static Four-Point Bend Test of IMFD
- Bending Fatigue mechanical testing of IMFD
- Fatigue testing of IMFD Assembly with corrosion assessment

Clinical data are not needed to support the safety and effectiveness of the subject device.

Based on the same intended use, materials, similar technological characteristics, and supportive performance testing, the Estremo Fibular Nail system has been established as substantially equivalent to the predicate device.