February 21, 2025

Orthopediatrics Canada ULC dba Pega Medical
Enrique Garcia
VP Operations
1111 Autoroute Chomedey
Laval, QC H7W 5J8
Canada

Re: K241983
Trade/Device Name: Fassier-Duval Telescopic IM System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: January 21, 2025
Received: January 22, 2025

Dear Enrique Garcia:

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,

Farzana Sharmin -S

Digitally signed by Farzana Sharmin -S
Date: 2025.02.21 14:53:00 -05'00'

Farzana Sharmin, Ph.D.
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.

510(k) Number *(if known)*
K241983

Device Name
Fassier-Duval Telescopic IM System

Indications for Use *(Describe)*
This implant is indicated as a temporary implant to aid in the healing of long diaphysis fractures, osteotomies, malunions and nonunions and to prevent further fractures in femur, tibia and humerus in pediatric patients suffering from Osteogenesis Imperfecta and other pediatric bone diseases without disrupting the bone growth plate. It can be used in procedures such as bone lengthening/shortening concomitantly with external fixators in pediatric or small stature patients with limb length discrepancy.

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) #: K241983

510(k) Summary

Prepared on: 2025-02-21

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Orthopediatrics Canada ULC
Applicant Address	1111 Autoroute Chomedey Laval QC H7W 5J8 Canada
Applicant Contact Telephone	450-688-5144
Applicant Contact	Mr. Enrique Garcia
Applicant Contact Email	egarcia@orthopediatrics.ca

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Fassier-Duval Telescopic IM System
Common Name	Intramedullary fixation rod
Classification Name	Rod, Fixation, Intramedullary And Accessories
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
K211292	Fassier-Duval Telescopic IM System	HSB
K041393	Fassier-Duval Telescopic IM System	HSB
K020885	Fassier-Duval Telescopic IM System	HSB
K192710	The Simple Locking Intramedullary (Slim) System	HSB

Device Description Summary

21 CFR 807.92(a)(4)

The Fassier-Duval Telescopic IM System is a telescopic rod for use in fixation of long bone fractures. The design of the nail includes a female component (which is attached to the proximal -trochanteric- cortex of the bone) and a male component (which is attached to the distal cortex of the bone). Anchorage of the components is achieved through screw-type fixation. The nail is composed of two sliding components that allow for extension of its length as the bone structures heal and normal patient growth occurs. The Fassier-Duval Telescopic IM System can be attached to bony structures without disrupting the bone growth plates.

The device is sold both sterile and Non sterile.

This 510(k) Premarket Notification is submitted for updating the intended use of the subject device to include other bone diseases and and MR safety labelling information compared to the currently cleared Fassier-Duval Telescopic IM System, which is indicated for patients with Osteogenesis Imperfecta. The previously cleared predicate device Simple Locking Intramedullary (SLIM) System (K192710) is used for deformity correction and fracture fixation in patients with bone diseases other than Osteogenesis Imperfecta which covers the new intended use of the subject device.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

This implant is indicated as a temporary implant to aid in the healing of long diaphysis fractures, osteotomies, malunions and nonunions and to prevent further fractures in femur, tibia and humerus in pediatric patients suffering from Osteogenesis Imperfecta and other pediatric bone diseases without disrupting the bone growth plate. It can be used in procedures such as bone lengthening/shortening concomitantly with external fixators in pediatric or small stature patients with limb length discrepancy.

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

The subject device, Fassier-Duval Telescopic IM System, and the previously cleared predicate devices—Fassier-Duval Telescopic IM System (K211292) as the primary predicate, Fassier-Duval Telescopic IM System (K041393 & K020885), and Simple Locking Intramedullary (SLIM) System (K192710) as reference/secondary predicates—are substantially equivalent. These devices share the same intended use, principles of operation, patient population (when used for deformity correction and fracture fixation), and many fundamental technological characteristics.

There are no differences between the primary predicate and the subject device in terms of system components, dimensions, design features, cross-sectional geometry, sterilization, or materials. The indications for use are also similar to those of the predicate devices, all intended for deformity correction and fracture fixation.

The intended use of the subject device has been updated to include other bone diseases compared to the currently cleared Fassier-Duval Telescopic IM System, which is indicated for patients with Osteogenesis Imperfecta. The previously cleared predicate device Simple Locking Intramedullary (SLIM) System (K192710) is used for deformity correction and fracture fixation in patients with bone diseases other than Osteogenesis Imperfecta which covers the new intended use of the subject device.

In addition, the successful usage of the subject device pertaining to such conditions is supported by the already available clinical literature. The clinical literature data provided in this submission support the amended intended use and do not raise different questions for safety and effectiveness.

The information provided above supports that the Fassier-Duval Telescopic IM System is as safe and effective as the predicate devices. Information and data provided within the submission support that the differences between the subject and predicate device and reference devices do not raise different questions for safety and effectiveness. Therefore, it is concluded that the Fassier-Duval Telescopic IM System is substantially equivalent to the predicate device.

Technological Comparison 21 CFR 807.92(a)(6)

The subject device, Fassier-Duval Telescopic IM System, is substantially equivalent to the previously cleared predicate device, Fassier-Duval Telescopic IM System (K211292), as well as the reference/secondary predicates (K041393, K020885, and K192710). The subject device shares the same technological characteristics as the predicate device, including design, materials, principle of operation, and other relevant technological aspects. There are no deviations or modifications from the technological features of the predicate device.

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

The Fassier-Duval Telescopic IM System has been evaluated in an MR environment. The following FDA-recognized standards were used as the basis for MR conditional testing:

ASTM F2119-07 (Reapproved 2013): Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants.

ASTM F2052-14: Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment.

ASTM F2213-06 (Reapproved 2011): Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment.

ASTM F2182-11a: Standard Test Method for Measurement of Radio Frequency Induced Heating Near Passive Implants During Magnetic Resonance Imaging.

The implants of the Fassier-Duval Telescopic IM System were evaluated for use in an MR Environment and were determined to be MR Conditional.

For New Intended Use:

Non-clinical Performance Data:

No design changes have been made since the previous submission.

Clinical Performance Data

The successful usage of the subject device pertaining to such conditions is supported by the already available clinical literature. The clinical literature data provided in this submission support the amended intended use and do not raise different questions for safety and effectiveness.

Conclusion:

The information provided above supports that the Fassier-Duval Telescopic IM System is as safe and effective as the predicate devices. The implants of the Fassier-Duval Telescopic IM System were evaluated for use in an MR Environment and were determined to be MR Conditional. Information and data provided within the submission support that the differences between the subject and predicate devices do not raise different questions for safety and effectiveness. Therefore, it is concluded that the Fassier-Duval Telescopic IM System is substantially equivalent to the predicate device.