Orthofix SRL
℅ Mitchell Dhority
Senior Director, Regulatory
Orthofix US LLC
3451 Plano Parkway
Lewisville, Texas 75056

May 3, 2024

Re: K232648
Trade/Device Name: RODEO Telescopic Nail
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: April 5, 2024
Received: April 8, 2024

Dear Mitchell Dhority:

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.

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: 2024.05.03 12:06:35 -04'00'

Farzana Sharmin, PhD
Assistant Director
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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)*

K232648

Device Name

RODEO Telescopic Nail

Indications for Use *(Describe)*

The RODEO Telescopic Nail is indicated for fractures, osteotomies, malunions and non-unions in femur and tibia in pediatric patients suffering from osteogenesis imperfecta.

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.

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510(K) SUMMARY

ORTHOFIX SRL
RODEO™ Telescopic Nail

Submitter information

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Date prepared	2024, April 5th

Trade Name, Common Name, Classification

Trade Name: RODEO™ Telescopic Nail
Common Name: Telescopic Intramedullary (IM) Nail
Classification Name: Intramedullary fixation rod
Regulation Number: 21 CFR 888.3020
Product Code: HSB
Classification: Class II
Panel code: Orthopedic

Primary Predicate

Primary Predicate	510(k) Number	Manufacturer
Telescopic Intramedullary System	K211292	Pega Medical Fassier Duval

Reference devices

Reference Devices	510(k) Number	Manufacturer
ORTHOFIX MODULSYSTEM	K955848	Orthofix s.r.l.
EDGE ORTHOPAEDICS BITE COMPRESSION SCREW	K132893	Orthofix s.r.l.
JPS JuniOrtho Plating System	K200246	Orthofix s.r.l.

Device description	The subject RODEO™ Telescopic Nail is a self-extending rod intended to provide bone fixation.
	The nail includes the telescopic rod, which consists of two parts (male and female) and bone anchors, which could be either a cap or an epiphyseal screw suitable to the anatomical application. The nail is provided in sterile and non-sterile version and is available in five diameters (3.5mm, 4.0mm, 4.5mm, 5.0mm and 6.0mm), identified by the outer diameter of the female part of the rod, and five lengths for each diameter model (from 100 mm up to 350 mm).
	
	Application and removal are performed with Orthofix general orthopedic instrumentation.
	
	The subject RODEO™ Telescopic Nail consists of three different components which are intended to be assembled to form the implant:
	• Male component - A solid shaft with a built-in bone anchor for bone connection; the bone anchor has the same design as the cap (described below).
	• Female component - A hollow shaft designed to host the male component.
	• Bone anchors – Two options are available depending on the desired application:
	  ○ Cap - A self-locking screw to be connected with the female component at the opposite aspect of the extremity relative to the male component.
	  ○ Epiphyseal Pin – A threaded pin to be inserted into the distal extremity hole to hold the female component in position and prevent migration (see Figure 3)
	
	When the male and female components are assembled, the resulting implant is a telescopic rod. Male and female components are free to move both axially and rotationally; this allows the nail to extend axially as the patient growth occurs while allowing rotation around the bone anchors.
	
	The subject implants are made from AISI 316LVM stainless steel, conforming to ASTM F138 and ISO 5832-1.

Indications for use	The RODEO Telescopic Nail is indicated for fractures, osteotomies, malunions and non-unions in femur and tibia in pediatric patients suffering from osteogenesis imperfecta.

Technological Characteristics	The following table provides a comparison and assessment of fundamental scientific principles and technological characteristics of the subject and the primary predicate devices. Any differences have been demonstrated to not raise different questions of safety or performance by virtue of objective evidence (e.g., bench testing, etc.). Therefore, the technological characteristics of the subject RODEO Telescopic Nail are equivalent to the primary predicate Pega Medical Fassier Duval Telescopic Intramedullary System (K211292).

Technological Characteristics		**Subject Device RODEO Telescopic Nail**	**Primary Predicate Device Pega Medical Fassier Duval Telescopic Intramedullary System**
1.	Indications for use	This implant is indicated for fractures, osteotomies, malunions and non-unions in femur and tibia in pediatric patients suffering from osteogenesis imperfecta	This implant is indicated as a temporary implant to aid in the healing of long diaphysis fractures, osteotomies, malunions and non-unions and to prevent further fractures in femur, tibia and humerus in pediatric patients suffering from Osteogenesis Imperfecta 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
	Assessment: The subject indications are included in the primary predicate indications for use. The difference in the anatomical site application, more extensive for the predicate device, do not constitute a new intended use. Equivalent - no different questions of safety and effectiveness have been raised.		
2.	Anatomical Sites	Long bones (Femur, tibia)	Long bones (Femur, tibia, humerus)
	Assessment: The anatomical sites for use for the subject device are within the anatomical sites cleared for the predicate device (femur, tibia). Equivalent - no different questions of safety and effectiveness have been raised.		
3.	Nail Material	Stainless Steel (316LVM, ISO 5832-1 and ASTM F 138)	Stainless Steel (316L, ASTM F138)
	Assessment: The material for the subject implants and predicate implants is the same (stainless steel), conforming to the same standard. 316LVM for the subject device undergoes a vacuum melt process for further purification. Equivalent - no different questions of safety and effectiveness have been raised.		
4.	General Design	Male component slides within mating female component as patient grows	Male component slides within mating female component as patient grows
	Assessment: The general design of the subject telescopic nail is in accordance with standard ASTM F1264-16, and is the same of the predicate device. Equivalent - no different questions of safety and effectiveness have been raised.		

5.	Bone Fixation	Proximal and distal screw-like anchor fixation features on male/female components; fixation with bi-cortical threaded cross pin to reduce potential nail migration	Proximal and distal screw-like anchor fixation features on male/female components; distal fixation option with bi-cortical k-wire to reduce potential nail migration
	Assessment: The bone fixation method for the subject device (bi-cortical fixation with Orthofix pins) is similar to the predicate device (bi-cortical k-wire). The change in fixation features have been evaluated through bench testing. Equivalent - no different questions of safety and effectiveness have been raised.		
6.	Nail Diameters	3.5, 4.0, 4.5, 5.0 and 6.0 mm (5 diameters)	3.2, 4.0, 4.8, 5.6 and 6.4 mm (5 diameters)
	Assessment: Size ranges of subject are similar to primary predicate device. Potential performance differences arising from variations in size offerings have been demonstrated through bench testing to not raise significant new questions. The subject device diameters are within the cleared range of the predicate device. Equivalent - no different questions of safety and effectiveness have been raised.		
7.	Nail Lengths	Up to 350mm	Up to 420 mm
	Assessment: Nail lengths of subject are similar to primary predicate device. The subject device nail lengths are within the cleared range of the predicate device. Equivalent - no different questions of safety and effectiveness have been raised.		
8.	Single Use	Yes	Yes
	Assessment: Subject device single use status is identical to predicate device. Equivalent - no different questions of safety and effectiveness have been raised.		
9.	Sterility Status	Sterile and Non-sterile	Sterile and Non-sterile
	Assessment: Subject device sterility status is identical to predicate device. Equivalent - no different questions of safety and effectiveness have been raised.		
10.	Sterilization Method	Radiation	Radiation
	Assessment: Subject device sterilization method is identical to predicate device. Equivalent - no different questions of safety and effectiveness have been raised.		

Reference devices were used for further evidence on how the technological characteristics of the subject device compare to legally marketed devices:

- The subject device biocompatibility characteristics refer to the same material with similar nature of contact of the reference device ORTHOFIX MODULSYSTEM' pins (K955848).
- The subject device epiphysial pin has the same or similar geometries, same material, same manufacturing process of the reference device EDGE ORTHOPAEDICS BITE COMPRESSION SCREW's guide wire (K132893).
- The subject device manufacturing process includes a validated cleaning process identical to previously cleared JPS Pediatric Plates (K200246).

Performance Analysis	Mechanical testing of the subject devices to demonstrate equivalence in function and safety for the intended use of the RODEO Telescopic Nail in respect to its primary predicate Pega Medical Fassier Duval Telescopic Intramedullary System (K211292) have been performed for the following functional attributes and are included in section “Bench Testing” of this eSTAR application form, as below: Both male and female components of the subject and predicate devices underwent mechanical testing consisting of the following as per standard ASTM F1264-16: - Stiffness evaluated through 4-point bending configuration - Yield Strength evaluated through 4-point bending configuration - Fatigue curve definition (1,000,000 cycles) End caps of the subject device were also tested by assessing welding torque resistance (the end cap is welded to the male component) and cap retention resistance (static test since the end cap is screwed onto the female component). Push-out testing (ability of cap to grip bone under axial push-out from a sawbone) was also conducted on both subject and predicate devices. Torsion properties, driving torque, pullout properties and bending of the subject epiphysial pin were compared against a reference device (guide wire, 510(k) clearance K132893) which fulfills all specification requirements called out in the operative technique of the primary predicate device. The performance of the nails were compared and the results are in line with the defined targets. Furthermore, additional static and dynamic testing was conducted on the worst case (smallest diameter) fully-assembled subject and predicate devices as per ASTM F1264-16. This same testing was also conducted on the largest diameter fully-assembled subject and predicate devices. As is reflected by the testing, the subject device results were equivalent or better than those of the comparable predicate device.
Conclusion	Based upon equivalences in: intended use, operating principles, and the non-clinical performance data, the subject RODEO Telescopic Nail has been shown to be substantially equivalent to the legally marketed predicate device.