Pega Medical Inc.
Enrique Garcia
Vice President of Operations
1111 Autoroute Chomedey
Laval, Quebec H7W 5J8
Canada

May 26, 2021

Re: K211292
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: April 23, 2021
Received: April 28, 2021

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

For Michael Owens
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K211292

Device Name

The 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 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.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) SUMMARY

Applicant:	Pega Medical Inc. 1111 Autoroute Chomedey Laval, Quebec, Canada, H7W 5J8 Phone: 1-877-739-5175
Contact Person:	Enrique Garcia
Proprietary Name:	Fassier-Duval Telescopic IM System
Common Name:	FD Telescopic Nail, FD Rod
Device Classification:	Class II
Panel:	Orthopedic
Regulation Number:	21 CFR 888.3020
Device Classification Name:	Intramedullary fixation rod
Device Product Code:	HSB
Establishment Registration Number:	9048931
Date Prepared:	May 18, 2021

Indications for Use:

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 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.

Description:

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 Pega Medical Fassier-Duval Telescopic IM System can be attached to bony structures without disrupting the bone growth plates.

This Special 510(k) Premarket Notification is submitted for the additional offering of gamma sterilized Ø3.2 – Ø6.4 stainless steel Fassier-Duval implant components. All subject components have previously been cleared as non-sterile implants. All other components of the Fassier-Duval Telescopic IM System will remain non-sterile to be sterilized by end-user.

Basis for substantial equivalence:

The technological characteristics (materials, design, sizing) of the Fassier-Duval Telescopic IM System are identical to the predicate Pega Medical Fassier-Duval Telescopic IM System (K020885 & K041393).

The rationale for substantial equivalence is based on consideration of the following characteristics:

- Intended Use: The intended use is identical to the predicate (K020885 & K041393).
- Indications for Use: Indications for Use are identical to the predicate (K020885 & K041393).

- Materials: Materials are identical to the predicate (K020885 & K041393).
- Design Features: Design features are identical to the predicate (K020885 & K041393).
- Function: The function is identical to the predicate (K020885 & K041393).
- Sterilization: The proposed Fassier-Duval Telescopic IM System seeks to add sterile packaged nails for distribution. All subject components have previously been cleared as non-sterile implants. All other components will remain non-sterile to be sterilized by end-user.

Non-clinical Performance Data:

No significant design changes have been made since the previous submission. Gamma sterilization validation, sterile packaging validation, integrity of the sterile barrier over time validation, and rinsing validation were performed to qualify the new packaging and sterilization method for the Fassier-Duval Telescopic IM system. Bacterial Endotoxin Testing was conducted in accordance with ANSI/AAMI ST72:2019.

Clinical Performance Data:

No clinical testing is provided as a basis for substantial equivalence.

Conclusion:

Pega Medical has established that the Fassier-Duval Telescopic IM System is substantially equivalent to the legally marketed predicate, Pega Medical Fassier-Duval Telescopic IM System (K020885 & K041393) based on the similarities of design, intended use, materials, sizing. Risk analysis and design control activities including verification activities were conducted to mitigate identified new risks associated with packaged sterile devices.