Pega Medical Inc.
Ariel R. Dujovne
President and CEO
1111 Highway Chomedey
Laval, Quebec, Canada H7W 5J8

June 24, 2020

Re: K192710
Trade/Device Name: The Simple Locking IntraMedullary (Slim) System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: May 21, 2020
Received: May 26, 2020

Dear Ariel Dujovne:

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,

Michael Owens
Acting 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)*

K192710

Device Name
The Simple Locking IntraMedullary (SLIM) System

Indications for Use *(Describe)*

The Simple Locking IntraMedullary (SLIM) System is intended as a temporary implant for alignment, stabilization and fixation of long bones that have been surgically prepared (osteotomy) for correction of deformities, or have sustained fractures due to trauma or disease. This includes:

- Femur and tibia in the pediatric population (child and adolescent), and small-stature adults such as patient with small intramedullary canals affected by skeletal dysplasias, osteogenesis imperfecta or other bone diseases.
- Humerus, ulna, fibula in all patient populations

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Wednesday, June 24, 2020

510(k) SUMMARY

Applicant :	Pega Medical Inc. 1111 Highway Chomedey Laval, Quebec, Canada, H7W 5J8 Phone : 1-877-739-5175 Fax: +1 450 233-6358
Contact Person :	Ariel R. Dujovne
Proprietary Name :	The Simple Locking IntraMedullary (SLIM) System
Common Name :	SLIM Rod
Device Classification :	Class II
Panel:	Orthopedic
Classification Name :	21 CFR-888.3020 Intramedullary fixation rod
Device Product Code :	HSB
Establishment Registration Number :	9048931

Intended Use:

The Simple Locking IntraMedullary (SLIM) System is intended as a temporary implant for alignment, stabilization and fixation of long bones that have been surgically prepared (osteotomy) for correction of deformities, or have sustained fractures due to trauma or disease. This includes:

- Femur and tibia in the pediatric population (child and adolescent), and small-stature adults such as patient with small intramedullary canals affected by skeletal dysplasias, osteogenesis imperfecta or other bone diseases.
- Humerus, ulna, fibula in all patient populations

Description:

The Simple Locking Intra-Medullary (SLIM) system consists of intramedullary fixation devices for use in long bones. The solid shaft, bevelled point, and pre-determined or blank length options is designed for easy insertion in the medullar canal. Anchorage of the device is achieved through a conical cortical thread to obtain a stable fixation in the epiphyses or cortical bone, which aims to reduce the risk of migration. Internal features, such as a hexagonal drive and an internal mechanical thread in the head of the device, are designed for capture and guidance during insertion and retrieval. Additional proximal and distal locking holes allow pinning to ensure fixation with locking pins or locking pegs when required, and the Bullet screws allow fixation of smaller diameter shafts that cannot be cross-pinned due to their size. The SLIM implants are manufactured in medical grade Stainless Steel (SS316L, ASTM F138). The rods are available in seven diameters: 2.0, 2.6, 3.2, 4.0, 4.8, 5.6 and 6.4 mm, from 80mm up to 400 mm in length allows end user to customize the length of the rod.

Basis for substantial equivalent:
The Simple Locking IntraMedullary (SLIM) System is claimed to be substantially equivalent in design, indicated use and function to the following devices:

Primary predicate:

- The Simple Locking IntraMedullary (SLIM) System, K143355, Pega Medical Inc.

References:

- GAP Endo-Exo Medullary System, K160545, Pega Medical Inc.
- Stainless Steel Elastic Intramedullary Nail System, K081452, Synthes (USA)

Summary of Technologies:
The technological characteristics of the Simple Locking IntraMedullary (SLIM) System are the same or similar to the predicate devices.

Non-clinical Performance Data:

No additional testing was considered necessary for the SLIM Blanks, pins or pegs.

- SLIM blanks have the identical diameters and material as previously cleared SLIM rods; therefore, they will have the same mechanical resistance.
- The added pins and pegs have the same or larger diameter and the same material than previously cleared pins, therefore they will have the same or higher mechanical resistance.

As per the findings of the bench testing and the performance of the predicate, the data supports the use of this product as substantially equivalent to the predicate device; the anticipated benefits of such a system clearly outweigh the possible residual risks.

Additional testing was conducted for the addition of the Bullet screw to the system. In four-point static and fatigue testing, the Bullet screws were found equivalent for their intended uses. In comparison to the previously cleared locking pins, it was considered that the Bullet and the locking pegs perform equivalently than simple locking pin that is bent against the cortex rather than threaded into the cortex in terms of torsion, drive torque and axial pull-out.

A list of the tests carried for this application can be found below:

- Static four-point bending bench testing;
- Fatigue four-point bending bench testing;
- Pull-out & Push-out strength;
- Surgical technique validation on animal model;

- Evaluation of a Shaft to Bullet assembly and instrumentation: migration resistance of the assembly under static loading;
- Evaluation of a Shaft to Bullet assembly and instrumentation: migration resistance of the assembly under cyclic loading (fatigue);
- Static four-point bending bench test of the Bullet;
- Fatigue four-point bending bench test of the Bullet;
- Surgical technique validation of the SLIM and Bullet;
- Comparative loading in physiological relevant setting of the SLIM and Bullet against predicate;
- Functional testing of the cutting operation of the Intro-OP Implant Cutter (ICON) Prototype on a SLIM blank.

Clinical Performance Data:
No clinical testing is provided as a basis for substantial equivalence.

Conclusion:
Based on the similarities in the intended use, design, materials, manufacturing methods, and packaging, The Simple Locking IntraMedullary (SLIM) System has been established as substantially equivalent to the previously cleared predicate device. Furthermore, mechanical evaluation results demonstrate that the proposed SLIM System is substantially equivalent to the predicate devices.