DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

November 23, 2016

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

Re: K160545
Trade/Device Name: Gap Endo-Exo Medullary System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: April 18, 2016
Received: April 19, 2016

Dear Ariel R. 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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160545

Device Name
GAP Endo/Exo Medullary System

Indications for Use *(Describe)*
The GAP Endo-Exo Medullary System is indicated as a temporary implant to assure alignment, stabilization and fixation of long bones that have been surgically prepared (osteotomy) for correction of deformities or fractures caused by trauma or disease. The GAP Endo-Exo Medullary System is used for pediatric patients (child and adolescent) ages 2 to 21. It is indicated for correction of the following conditions:

- Diaphyseal fracture of the femur, tibia and humerus
- Fractures of the femoral neck
- Subtrochanteric, intertrochanteric and combination fractures
- Correction of deformities (OI, Coxa vara, Coxa valga)
- Nonunions and malunions

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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Wednesday, November 22nd, 2016

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Applicant :	Pega Medical Inc. 1111 Highway Chomedey Laval, Quebec, Canada, H7W 5J8 Phone :1-877-739-5175 Fax :1-888-258-0760
Contact Person :	Ariel R. Dujovne
Proprietary Name :	GAP Endo-Exo Medullary System
Common Name :	Intramedullary Nail
Device Classification :	Class II
Classification Name :	Rod, Fixation, Intramedullary And Accessories 21 CFR 888-3020
Device Product Code :	HSB
Establishment Registration Number :	9048931

Intended Use:

The GAP Endo-Exo Medullary System is indicated as a temporary implant to assure alignment, stabilization and fixation of long bones that have been surgically prepared (osteotomy) for correction of deformities or fractures caused by trauma or disease. The GAP Endo-Exo Medullary System is used for pediatric patients (child and adolescent) ages 2 to 21. It is indicated for correction of the following conditions:

- Diaphyseal fracture of the femur, tibia and humerus
- Fractures of the femoral neck
- Subtrochanteric, intertrochanteric and combination fractures
- Correction of deformities (OI, Coxa vara, Coxa valga)
- Nonunions and malunions

Description:

The GAP Endo-Exo Medullary System consists of an intramedullary cannulated nail linked to various types of plates via lag and/or mechanical screws creating a combined Endomedullary/ Exomedullary osteosythesis device. The nail is available is diameters ranging from 4.8 to 12.0mm in 0.8mm increments. Lengths available range from 160 to 320mm. 2.5, 3 and 4mm cortical screws are used to secure the nail to the bone.

Basis for substantial equivalent:

The GAP Endo-Exo Medullary System is claimed to be substantially equivalent in design and function to the following predicate devices:

1. The GAP Endo-Exo Medullary System, Pega Medical Inc. [K111232]
2. The Fassier-Duval Telescopic IM System (Stainless steel or Ti pediatric Nail), Pega Medical Inc. [K041393/K020885]

The intended use remains unchanged from the original GAP Endo-Exo Medullary System (K111232). Design changes have been validated via in-vitro biomechanical testing, when deemed necessary. The dimensional modification to the device maintains the effectiveness and increases the safety of the device.

Summary of Technologies:
The technological characteristics of the GAP Endo-Exo Medullary System are the same or similar to the ones of the predicate devices. The subject device uses the exact same lag and mechanical screws to fix onto the various plates at the level of the proximal femur. However, for distal locking of the shaft, the subject device was redesigned for locking with Ø2.5mm unicortical pins instead of Ø3.0mm bicortical screws in the Ø4.8mm GAP Nail, which increases the mechanical resistance and fatigue life of the Ø4.8mm GAP Nail at the level of the distal pinning because of the reduction in the size of the locking holes when compared to the predicate device.

Non-clinical Performance Data:
The proposed modification on the design of the distal holes of the 4.8 mm GAP Nail was tested through bench testing in static and fatigue loading with an offset axial compression test set-up. The results indicate that the new design increases mechanical resistance and fatigue life compared to the predicate Ø4.8mm GAP Nail design [K111232].

No Animal or Clinical testing was performed.

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

Conclusion:
Based on the similarities of intended use, design, materials, manufacturing methods and packaging, the GAP Endo-Exo Medullary System has been established substantially equivalent to the previously cleared predicate devices. The literature supports the use of this product as safe and effective for its intended use; the anticipated benefits of such system outweigh any possible residual risks.