DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

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

September 8, 2017

Re: K170704
Trade/Device Name: The Locking Pediatric Osteotomy Plate (LolliPOP) System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: KTT
Dated: July 24, 2017
Received: July 26, 2017

Dear Mr. 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 (DICE) 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 (DICE) 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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K170704

Device Name
The Locking Pediatric Osteotomy Plate (LolliPOP) System

Indications for Use *(Describe)*
The Locking Pediatric Osteotomy Plate (LolliPOP) system is a modular hip blade-plate system intended for stable fixation of valgus, varus, derotation, flexion and extension of proximal femoral osteotomies (PFO) and fractures in the pediatric (ages 2 to 21 years old) population. Indications for use include the following:
*Inter and subtrochanteric valgus osteotomies
*Inter and subtrochanteric varus osteotomies
*Inter and subtrochanteric derotation osteotomies
*Inter and subtrochanteric flexion and extension osteotomies,
*Inter and subtrochanteric fractures.

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 OF SAFETY AND EFFECTIVENESS

Applicant: Pega Medical Inc.
1111 Highway Chomedey
Laval, Quebec, Canada, H7W 5J8
Phone: 1-877-739-5175
Contact Person: Ariel R. Dujovne
Proprietary Name: The Locking Pediatric Osteotomy Plate (LolliPOP) System
Common Name: Blade plate system
Regulation Number: 21 CFR 888.3030
Single/multiple component metallic bone fixation appliances and accessories.
Device Classification: Class II
Device Classification Name: Appliance, Fixation, Nail/Blade/plate Combination, Multiple Components
Device Product Code: KTT
Establishment Registration Number: 9048931

Intended Use:
The Locking Pediatric Osteotomy Plate (LolliPOP) system is a modular hip blade-plate system intended for stable fixation of valgus, varus, derotation, flexion and extension of proximal femoral osteotomies (PFO) and fractures in the pediatric (ages 2 to 21 years old) population. Indications for use include the following:

- Inter and subtrochanteric valgus osteotomies
- Inter and subtrochanteric varus osteotomies
- Inter and subtrochanteric derotation osteotomies
- Inter and subtrochanteric flexion and extension osteotomies
- Inter and subtrochanteric fractures

Description:
The Locking Pediatric Osteotomy Plate (LolliPOP) system is a modular hip blade-plate system intended for stable fixation of valgus, varus, derotation, flexion and extension, of proximal femoral osteotomies (PFO) and fractures in the pediatric population. PFOs are widely performed reconstructive surgeries in children with hip deformities, such as Coxa Valga, Coxa Vara and other congenital deformities. The implants are made of medical grade 316L Stainless Steel (ASTM F138) and are offered in four sizes: infant, child, adolescent and adolescent HD. The system is comprised of a set of plates, blades, connectors, locking cortical screws, polyaxial compressions screws, and all the instrumentation required for implantation and retrieval of the device.

Basis for substantial equivalence:
The Locking Pediatric Osteotomy Plate (LolliPOP) System is claimed to be substantially equivalent in design, indicated use and function to the following predicate devices:

Labeling Name	marketed by	510(k) number
Cannulated Pediatric Osteotomy (CAPOS) system ***(Primary predicate)***	Synthes USA LLC	**Angled Blade Plate** K914546
TC-100 plating and screw system	Smith & Nephew, Inc. Orthopaedic Division	**Locking Bone Plate System** K033669 (previously K993106)
Locking Cannulated Blade (LCB) plate system	OrthoPediatrics, Corp.	**Blade Plate System** K110959
Modular Blade Plate System	Synthes USA LLC	**Modular Blade Plate System** K080109

Summary of Technologies:
The technological characteristics of the Locking Pediatric Osteotomy Plate (LolliPOP) System are the same or similar to the ones of the predicate devices for the described intended uses. Furthermore, the Locking Pediatric Osteotomy Plate (LolliPOP) System and all predicate systems use screws as the primary fixation method. Finally, modularity of the LolliPOP System is equivalent to that of the Modular Blade Plate system.

Non-clinical Performance Data:
Verification calculations were completed to evaluate resistance of the Locking Pediatric Osteotomy Plate System in comparison to the predicate systems. The mechanical properties of all the blade, plate and screw components of the system were analysed in comparison to the predicate systems. Furthermore, the bench testing of the Locking Pediatric Osteotomy Plate in static and fatigue confirmed the validity of these calculations.

The following non-clinical Performance testing were completed:

- Single cycle and fatigue compression bend testing on the construct
- Screw performance (torsional strength, axial pullout, driving torque)
- Bending strength of the plate

Results of the bench testing on the Locking Pediatric Osteotomy Plate System and predicate Synthes CAPOS System demonstrate that the systems perform equivalently.

Finally, a systematic search of the scientific literature was carried out and a Clinical Evidence Review report was issued. This report intended to identify and analyze the published peer-reviewed scientific literature regarding the intended uses, and more specifically of the two predicate systems, in order to establish the safety and effectiveness of the subject system by addressing the clinical hazards identified in the device Risk Analysis.

As per the findings of the bench testing and the scientific literature review, the data supports the use of this product as safe and effective for its intended use; the anticipated benefits of such a system clearly outweigh the possible residual risks.

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 Locking Pediatric Osteotomy Plate (LolliPOP) System has been established as substantially equivalent to the previously cleared predicate devices. Furthermore, mechanical evaluation results demonstrate that the proposed system is substantially equivalent to the predicate devices.