October 24, 2022

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

Re: K220190
Trade/Device Name: The GIRO Growth Modulation System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: OBT, HWC
Dated: September 15, 2022
Received: September 16, 2022

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,

Shumaya Ali, M.P.H.
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220190

Device Name
The GIRO Growth Modulation System

Indications for Use *(Describe)*
The GIRO™ Growth Modulation System is intended as a temporary implant to aid in the correction of the angle of growth of long bones by modulating growth of the physis in pediatric (child and adolescent) patients. It is indicated for the following conditions:

- Femur and tibia: varus, valgus, flexion, or extension deformities of the knee.
- Humerus: valgus or varus deformities of the elbow.
- Radius and ulna: flexion or extension deformities of the wrist.
- Ankle: varus, valgus or plantar flexion deformities of the ankle.
- Limb length discrepancy of the femur and tibia.

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.

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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 GIRO™ Growth Modulation System
Common Name: GIRO™ System
Regulation Number: 21 CFR 888.3030
Single/multiple component metallic bone fixation appliances and accessories.
Device Classification: Class II
Device Classification Panel: Orthopedic
Device Classification Name: Plate, Bone, Growth Control, Pediatric, Epiphysiodesis
Device Product Code: OBT, HWC
Establishment Registration Number: 9048931

Intended Use:
The GIRO™ Growth Modulation System is intended as a temporary implant to aid in the correction of the angle of growth of long bones by modulating growth of the physis in pediatric (child and adolescent) patients. It is indicated for the following conditions:

- Femur and tibia: varus, valgus, flexion, or extension deformities of the knee.
- Humerus: valgus or varus deformities of the elbow.
- Radius and ulna: flexion or extension deformities of the wrist.
- Ankle: varus, valgus or plantar flexion deformities of the ankle.
- Limb length discrepancy of the femur and tibia.

Description:
The GIRO™ Growth Modulation System is a tether device used for guided growth and deformity correction. It includes two couplings linked via a flexible cable and anchored to the bone via screws and bi-cortical posts. By tethering the growth plate, angular deformities can be corrected. The implants are manufactured in medical grade 316L stainless steel (ASTM F138) and offered in two sizes: 4.5 and 6.0.

Basis for substantial equivalence:
The GIRO™ Growth Modulation System is claimed to be substantially equivalent in design, indicated use and function to the following devices:

	Labeling Name	Marketed by	MDL number	510(k) number
Primary Predicate device	Hinge Pediatric Plating System	Pega Medical Inc.	80588	K090440
Additional Predicate device	PediatrOS RigidTack/Flextack	Merete Medical GMBH	N/A	K151762
Reference device	OrthoPediatrics PediPlates System	OrthoPediatrics, Corp.	97840	K090666
Reference device	Guided Growth System Eight-Plate, Quad-Plate (Stainless Steel)	Orthofix Inc.	70083	K110805
Reference device	Fixation Staples, BLOUNT Staples Epiphyseal	Stryker Corp.	11011	K834513
Reference device	Zimaloy Epiphyseal Staple	Zimmer Inc.	10944	Grandfathered; literature shows product used since 1949(Blount, 1949)

Blount WP, Clarke GR. 1949. *Control of bone growth by epiphyseal stapling: a preliminary report*. J Bone Joint Surg 31A:464-478.

Summary of Technologies:
The technological characteristics of the GIRO™ System are similar to the ones of the predicate and reference devices for the described intended uses, with a flexible tether that is designed to better conform to the surface of the bone. For temporary epiphysiodesis, unlike predicate and reference devices, the use of bi-cortical telescoping posts is suggested over the use of screws or staples due to its better surface contact above and below the growth plate. The mating of the spherical heads of the screws and posts into the spherical seating of the couplings allows this low-profile implant to minimize interference with the surrounding tissues.

Non-clinical Performance Data:
Verification calculations were completed to evaluate resistance of the GIRO™ System in comparison to the predicate and reference systems, such as the Hinge Plate, PediPlates, Eight-Plate, RigidTack/FlexTack systems, and the Zimaloy Epiphyseal Staple. The mechanical properties of all the GIRO™ System posts, screws, cable, and couplings components were analysed in comparison to the predicate and reference systems as well as physiological loads documented in literature. Furthermore, bench testing of the GIRO™ System confirmed the validity of the analysis. Results of the bench testing of the GIRO™ System and primary predicate demonstrate equivalent performance.

As per the findings of the bench testing and the clinical performance of the primary predicate, the data supports the use of GIRO™ System as safe and effective for its intended use; the anticipated benefits of such a system clearly outweigh the possible residual risks.

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

- Static vertical tension of the GIRO
- Static tension of the GIRO assembly in foam block
- Insertion torque of the Screws
- Insertion torque of the Posts
- Removal torque of the Screws
- Removal torque of the Posts
- Axial pullout of the Screws
- Axial pullout of the Posts
- Breaking torque of the Screws
- Breaking torque of the Posts
- Static 3-point bending of the Screws
- Static 4-point bending of the Post assembly
- Surgical technique validation of the prototypes

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 GIRO™ System has been established as substantially equivalent to the previously cleared predicate and reference devices. Furthermore, mechanical evaluation results demonstrate that the proposed system is substantially equivalent or superior to the predicate and reference devices.