Cycla Orthopedics Ltd
% Elaine Duncan
President
Paladin Medical
PO Box 560
Stilwater, Minnesota 55082-0560

April 26, 2019

Re: K183094
Trade/Device Name: CyclaPlex Correction System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HTN
Dated: March 22, 2019
Received: March 26, 2019

Dear Elaine Duncan:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Daniel S. Ramsey -S
2019.04.26 12:05:54 -04'00'

FOR 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)*
K183094

Device Name

CyclaPlex Correction System

Indications for Use *(Describe)*
The CyclaPlex Correction System is intended for the following surgical indications: to assist in the correction of Hallux Valgus deformity by providing reduction of the 1st intermetatarsal angle.

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- TRADITIONAL-

SUBMITTED on behalf of:

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By: **Elaine Duncan, M.S.M.E., RAC**
President, Paladin Medical, Inc.
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Stillwater, MN 55082
Telephone: **715-549-6035**
Fax: **715-549-5380**

CONTACT PERSON: **Elaine Duncan**
DATE PREPARED: **October 30, 2018**

TRADE NAME:	CyclaPlex Correction System
COMMON NAME	Button/Anchor/suture
CLASSIFICATION NAME:	Single/multiple component metallic bone fixation appliances and accessories:
CLASS	CLASS II
REGULATION/PROCODE	21 CFR 888.3030/ PRO CODE: HTN

INDICATIONS FOR USE:
The CyclaPlex Correction System is intended for the following surgical indications: to assist in the correction of Hallux Valgus deformity by providing reduction of the 1st intermetatarsal angle.

DESCRIPTION of the DEVICE:
The CyclaPlex Correction System is comprised of the Implant, Accessories and Instrument Set. The Implant device pulls the 1st metatarsal inward towards 2nd metatarsal and reduces the intermetatarsal angle to medically accepted values. The implant is comprised of two metallic bone screws with internal polymeric housing connected by UHMW polyethylene multiple sutures cord. The cord is looped and secured at Anchor 2 and secured to Anchor 1 by multiple surgical knots. Two implants (paired) are implanted to reduce local loads on the bone and reduce loads on the device as well.

SUBSTANTIALLY EQUIVALENT TO:
The CyclaPlex Correction System is substantially equivalent to Instratek- Michelangelo Bunion System (MAB). Premarket notification: K 091763. MAB is comprised of two buttons/plates connected by UHMW polyethylene cord. The CyclaPlex Correction System is the same as the predicate device in areas of classification, anatomical site, where used, principle of operation, intended use, contraindications and material: both utilize UHMWPE suture and two metallic end caps, both intended for use in the same anatomical location. CyclaPlex has slight differences in structure, surgical instrumentation and sterilization. Additional differences include the end cap geometry, a more modular design with a polymeric insert. Also, the CyclaPlex requires two implants whereas the predicate allows various configurations (one or more).

510(k) Summary-Continued

A detailed analysis and testing have demonstrated that the CyclaPlex Correction System has the same intended use and raises no new safety or effectiveness questions.

SUMMARY of TESTING to DEMONSTRATE SAFETY and EQUIVALENCE:

The mechanical static and fatigue testing were performed to demonstrate that the proposed device can withstand the biomechanical forces, at least as well as the predicate device. Preclinical animal tests showed that CyclaPlex device performance in minipig animals is at least as good as predicate device Surgical instrument human factor analysis was performed to evaluate the safety and usability of surgical instruments in comparison to predicate device, Analysis had demonstrated that instruments provide safe use at least as good as the predicate device.

Cadaver tests further demonstrated that the implant structure, surgery procedure and instruments are suitable to perform implantation as intended. Biological evaluation demonstrated that proposed device materials post manufacturing and cleaning meet ISO 10993-1 requirements. Animal testing further extended the biological safety assessment as well as demonstrated the device implantation procedure and surgical instrument usability. Packaging, sterilization and cleaning validation were also conducted for implant and instruments and met requirements. MR were performed according ASTM relevant standards (F2119-07, F2052-15, F2182-11a, F2213-06) and included Magnetic field interactions, MR artifacts and MR heating, demonstrating that CyclaPlex implant device is "MR conditional."

CONCLUSION:

Based upon the comparative analysis and testing the CyclaPlex Correction System is substantially equivalent to the currently marketed predicate device.