June 25, 2020

McGinley Orthpaedic Innovations, LLC
% David McGurl
Director, Regulatory Affairs
MCRA, LLC
1050 K Street NW, Suite 1000
Washington, District of Columbia 20001

Re: K200834
Trade/Device Name: Lever Action Plate System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HRS
Dated: June 12, 2020
Received: June 15, 2020

Dear David McGurl:

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, MPH
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200834

Device Name
Lever Action Plate System

Indications for Use *(Describe)*
The Lever Action Plate System is indicated for:
1. Fixation of fractures or non-unions of the distal radius
2. Osteotomies of the distal radius to correct malunion

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

Device Trade Name: Lever Action Plate System

Manufacturer:
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Date Prepared: 6/25/2020

Classification: 21 CFR 888.3030 Single/multiple component metallic bone fixation appliances and accessories.

Common Name: Plate, Fixation, Bone

Class: II

Product Code: HRS

Predicate Devices: Trimed Bearing Plate: Trimed Volar Bearing Plate (K040112)

Indications for Use: The Lever Action Plate System is indicated for:
1. Fixation of fractures or non-unions of the distal radius
2. Osteotomies of the distal radius to correct malunion

Device Description:
The Lever Action Plate System is a distal radius plate implanted in the treatment of distal radius fractures, non-unions, or osteotomies. The system consists of the plates, screws, beams, beam screws and instrumentation. The plates have either 1 or 2 beam slots which allow for implantation of the beams into the distal radius bone. The beams and their supporting beam screws are intended for maintaining volar correction intra-operatively. The plate and beam(s) are used in conjunction with screws and beam screws to fixate fragments in the wrist. The implants are composed of Ti-6Al-4V and are available in multiple configurations and sizes.

Substantial Equivalence:
The subject device has the identical indications for use as the predicate device. Both devices are intended to be used in the distal radius for fracture and osteotomies. Both the subject and predicate device use the same inherent technology, screw and plate components to fixate bone fragments to allow for bone healing. Both systems are manufactured from the same metallic components (i.e. Ti alloy). There are differences in the design of the plate and screws but these differences do not raise new questions of safety and effectiveness. Testing was provided to support the plate and screw constructs have equivalent strength.

Therefore, the Lever Action Plate System is substantially equivalent to the predicate devices cited on the previous page with respect to indications, design, function, and performance.

Preclinical Testing:
Static and dynamic mechanical compression bend testing was conducted of the Lever Action Plate System (i.e. subject plates, the subject plates beams, and beam screws) and a predicate. The testing demonstrated that subject plates have equivalent strength in comparison to the predicate.

Static Torsion, Driving Torque, Removal Torque, and Static Axial Pullout Testing was conducted on Level Action Plate System screws per ASTM F543. The testing demonstrate that the screws are of sufficient strength for their intended use. Disassembly pushout testing was conducted on the beams/plate interface. The testing demonstrate that the fixation components are of sufficient strength, fixation and usability for their intended use.

Clinical Testing:
Clinical testing was not necessary to support equivalence.

Conclusion:
The Lever Action Plate System possesses the similar intended use and technological characteristics as the predicate device. Additionally, the preclinical testing support the substantial equivalence of the Lever Action Plate System to the predicates. Therefore, the Lever Action Plate System is substantially equivalent for its intended use.