January 31, 2022

RELJA Innovations, LLC
% Allison Komiyama
Principal
AcKnowledge Regulatory Strategies, Inc.
2251 San Diego Ave, Suite B-257
San Diego, California 92110

Re: K211628
Trade/Device Name: MIS Precision Chevron Bunion System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: December 30, 2021
Received: December 30, 2021

Dear Allison Komiyama:

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,

For: 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)*
K211628

Device Name
MIS Precision Chevron Bunion System

Indications for Use *(Describe)*
The MIS Precision Chevron Bunion System is indicated for fixing and stabilizing the elective osteotomies of the mid-foot bones and the metatarsal and phalanges of the foot only.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary
K211628

1. Submitted By:

RELJA Innovations LLC
17145 W. Bluemound Rd.
Suite #J-265
Brookfield, WI 53005

Date: January 27, 2022

Contact Person:

David Pancratz
Chief Operating Officer
Phone: 210-383-3907
Email: dave@reljainnovations.com

Regulatory Consultant:

Allison Komiyama, Ph.D., RAC
Lucie Dalet, Ph.D.
RQM+
Phone: 412-816-8253
Email: akomiyama@rqmplus.com
ldalet@rqmplus.com

2. Proprietary Name: MIS Precision Chevron Bunion System

Common Name: Screw, Fixation, Bone

Classification Name and Reference: 21 CFR 888.3040 – Class II
Smooth or threaded metallic bone fixation fastener

Device Product Code, Device Panel: HWC, Orthopedic

3. Primary Predicate: Stryker Fixos Screw System, K070039.

4. Device Description:

The MIS Precision Chevron Bunion System™ is a kit designed to allow surgeons to perform a chevron bunion osteotomy, and subsequent fixation of the osteotomy, with a minimally invasive surgical technique. The MIS Precision Chevron Bunion System™ consists of a

single, sterile-packaged SKU that contains both implants and instruments needed for the procedure.

The implants in the kit are cannulated headless compression screws, made from titanium (Ti-6AL-4V ELI). There are two implants in the kit, however only one is used in a surgical procedure. Two implants are provided to allow the physician to select the proper size for the patient at the time of surgery. The implants are 3.5 mm diameter, with lengths of 24 mm and 27 mm.

There are also single-use instruments, made of injection molded polycarbonate, PEEK, and stainless steel included in the MIS Precision Chevron Bunion System™. Instruments include an osteotomy guide (one each for left and right feet), a targeting guide, a screw guide, screwdriver, drill bit, and several K-wires and a guidewire.

Additional general surgical instrumentation is utilized, but not part of the RELJA system, such as sagittal saw, drivers, and scalpel.

5. Indications for Use

The MIS Precision Chevron Bunion System is indicated for fixing and stabilizing the elective osteotomies of the mid-foot bones and the metatarsal and phalanges of the foot only.

6. Technological Characteristics Comparison

The MIS Precision Chevron Bunion System™ utilizes a 3.5 mm diameter cannulated compression screw made of titanium alloy for fixation of a chevron osteotomy of the hallux. Similarly, the Memometal Fixos Screw System recommends a 3.5 mm diameter cannulated compression screw made of titanium alloy for fixation of a chevron osteotomy of the hallux. The Memometal Fixos Screw System also includes numerous other sizes of screws recommended for other surgical procedures.

The MIS Precision Chevron Bunion System™ also includes single-use sterile instrumentation to assist in making the chevron osteotomy and placing the implant. The Memometal Fixos system utilizes metal and/or reusable instruments for performing the same procedure.

7. Substantial Equivalence – Non-Clinical Evidence

- Biocompatibility: The subject device was subjected to biocompatibility testing in compliance to ISO 10993-1 *Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process*, ISO 10993-5 *Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity* and ISO 10993-10 *Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization*.

- Sterility and shelf life: The final, finished subject device was subjected to sterility testing in compliance with ISO 11137-1 *Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices* and ISO 11137-2 *Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose*. Bacterial endotoxin testing in accordance with recommendations in the FDA Guidence Document, *Pyrogen and Endotoxin Testing: Questions and Answers* and shelf-life testing confirming five-year shelf-life was also completed on the final finished device. Accelerated aging according to ASTM F1980 *Standard Guide for Accelerated Aging of Sterile Barrier Systems and Medical Devices* was completed. Packaging integrity on the aged devices was verified according to ASTM F1886 *Standard Test Method for Determining Integrity of Seals for Medical Packaging by Visual Inspection*, ASTM F2096 *Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test),* and ASTM F88 *Standard Test Method for Seal Strength of Flexible Barrier Materials*.

- Performance evaluation: Testing included Static Torsion and Driving Torque per ASTM F543 *Standard Specification and Test Methods for Metallic Medical Bone Screws*, and predicted Axial Pullout Strength in accordance with FDA Guidance Document. The results of the Static Torsion testing show that the RELJA screw is stronger than the predicate in torsion. The results of Driving Torque and Axial Pullout Strength analysis show that the RELJA screw meets FDA requirements for non-spinal metallic screws.

- Performance evaluation: Performance and usability testing of the subject device by trained foot and ankle physicians were conducted in twenty-five simulated surgical procedures using cadaveric tissue, on five separate dates. The procedure was successfully completed on male (14 total) and female (11 total) feet ranging in size from small to large. Results show that the precision osteotomy guide is able to be properly positioned on any size foot by following the surgical technique. Fixation and fluoroscopy images showed proper location of the osteotomy and placement of the implant after each simulated procedure.

The safety and effectiveness of the MIS Precision Chevron Bunion System™ is adequately supported by testing, substantial equivalence information, materials information and comparison of design characteristics provided within this premarket submission.

8. Substantial Equivalence – Clinical Evidence
   Not applicable.

9. Substantial Equivalence – Conclusions

   The design characteristics of the subject devices do not raise any new types of questions regarding safety or effectiveness. From the evidence submitted in this 510(k), the subject devices can be expected to perform at least as well as the predicate systems and are substantially equivalent.