July 22, 2026

Relja Innovations, LLC
% Jen Mcbride
Regulatory Consultant
MRC Global
9160 Hwy. 64 Suite 12
P.O. Box 330
Lakeland, Tennessee 38002

Re: K262075
Trade/Device Name: Lapidus Screw Kit
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: June 19, 2026
Received: June 22, 2026

Dear Jen Mcbride:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K262075

Device Name
Lapidus Screw Kit

Indications for Use *(Describe)*

The Lapidus Screw Kit is intended for use in first tarsometatarsal (Lapidus) arthrodesis and elective osteotomies involving the midfoot, metatarsals, and phalanges of the foot.

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.

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510(k) Summary

Lapidus Screw Kit

July 21, 2026

Company: RELJA Innovations, LLC
11220 W. Burleigh St.
Wauwatosa, WI 53222

Company Contact: Robby Amiot – CEO
rob@reljainnovations.com
414-305-4909

Official Correspondent: Jen McBride – MRC Global, LLC
jen.mcbride@askmrcglobal.com
901-481-5902

Trade Name: Lapidus Screw Kit

Common Name: Screw, Fixation, Bone

Classification: Class II

Regulation Number: 21 CFR 888.3040 (Smooth or threaded metallic bone fixation fastener)

Panel: Orthopedic

Product Code: HWC

Device Description:

The Lapidus Screw System is a modification of the MIS Precision Chevron Bunion System™. Like the MIS Bunion System, the Lapidus Screw Kit 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 (Ti6AL-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. There are also single-use instruments, made of injection molded polycarbonate, PEEK, and stainless steel included in Lapidus Screw Kit.

The purpose of this submission is to expand the size offerings of the screws and to modify the indications for use.

Indications for Use:

The Lapidus Screw Kit is intended for use in first tarsometatarsal (Lapidus) arthrodesis and elective osteotomies involving the midfoot, metatarsals, and phalanges of the foot.

Substantial Equivalence:

The subject Lapidus Screw Kit is substantially equivalent to the following legally marketed predicate devices:

Primary Predicate:

Relja – MIS Precision Chevron Bunion System – K211628

Additional Predicates:

Stryker Trauma AG – Fixos Screw System – K133451

The subject Lapidus Screw Kits are identical in every way to the primary predicate device, except the subject screws are offered in different sizes with slightly modified indications for use. The predicate indications for use are inclusive of the subject indications for use and the size range of the predicates is inclusive of the subject device size range.

Performance Testing:

The subject screws do not create a new worst case condition when compared to the primary predicate device. Therefore, previously performed testing (mechanical performance, sterility, packaging, shelf life, and biocompatibility) on the primary predicate device applies to the subject device and no additional testing is needed.

Conclusion:

Based on the comparison to the predicate device, the subject device is determined to be substantially equivalent to the predicate device.