



May 21, 2019

Fusion Orthopedics, LLC
Eli Jacobson
Official Correspondent
4135 S. Power Rd., Suite 110
Mesa, Arizona 85212

Re: K182342

Trade/Device Name: IntraLock Lapidus System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: April 19, 2019
Received: April 22, 2019

Dear Eli Jacobson:

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,

Shumaya Ali, MPH
Assistant Director
DHT6C: Division of Stereotaxic, Trauma
and Restorative Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K182342

Device Name

IntraLock Lapidus System

Indications for Use (Describe)

The IntraLock Lapidus System is indicated for reduction and internal fixation of arthrodeses, osteotomies, intra- and extra-articular fractures, and nonunions of the small bones and joints in the foot. The two-part construct is specifically intended for use in Talonavicular, Calcaneocuboid, and Metatarsocuneiform arthrodesis.

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: IntraLock Lapidus System

In accordance with 21 CFR 807.92 of the Federal Code of Regulations

Date Prepared	April 16, 2019
Submitted By	Fusion Orthopedics, LLC 4135 S. Power Rd., Suite 110 Mesa, AZ 85212 800-403-6876
Primary Contact	Eli Jacobson 4135 S. Power Rd., Suite 110 Mesa, AZ 85212 800-403-6876 Tele e-mail: eli@fusionorthopedics.com
Trade Name	IntraLock Lapidus System
Common Name	Bone Screws
Classification Name	Smooth & threaded metallic bone fixation fasteners
Class	II
Product Code	HWC
CFR Section	21 CFR section 888.3040
Device Panel	Orthopedic
Primary Predicate Device	EXTREMITY MEDICAL Screw and Washer Implant System, Extremity Medical (K10700)
Secondary Predicate Device	FuzeFix Screw System, Fusion Orthopedics (K170038)
Device Description	The IntraLock Lapidus System is a two-part construct, consisting of a lag screw of two diameters and lengths ranging from 22mm to 50mm, as well as a mating washer component consisting of one diameter and lengths ranging from 16mm to 35mm. The IntraLock Implants are constructed of titanium alloy (Ti6Al4V). The specialized instruments are made of surgical grade stainless steel (ASTM F899).
Indications for Use	The IntraLock Lapidus System is indicated for reduction and internal fixation of arthrodeses, osteotomies, intra- and extra-articular fractures, and nonunions of the small bones and joints in the foot. The two-part construct is specifically intended for use in Talonavicular, Calcaneocuboid, and Metatarsocuneiform arthrodesis.

Materials	Ti-6Al-4V alloy (ASTM F136) Stainless steel (ASTM F899) 6061 Aluminum (ASTM B209)
Substantial Equivalence Claimed to Predicate Devices	The Intralock Lapidus System is substantially equivalent to the predicate devices in terms of intended use, design, materials used, mechanical safety and performances.
Non-clinical Test Summary	The following analyses were conducted: -Static torsion analysis. -Insertion torque analysis. -Pull-out analysis. The following tests were conducted: - Static 4-point bending test. - Dynamic 4-point bending test. - Pyrogenicity was evaluated using the Limulus amoebocyte lysate (LAL) assay. The testing demonstrated that the subject device meets the recommended maximum endotoxin level of 20 EU per device. The results of these evaluations indicate that the IntraLock Lapidus System is equivalent to predicate devices.
Clinical Test Summary	No clinical studies were performed
Conclusions:	Fusion Orthopedics LLC considers the IntraLock Lapidus System to be equivalent to the predicate devices listed above. This conclusion is based upon the devices' similarities in principles of operation, technology, materials and indications for use