July 23, 2021

Fusion Orthopedics, LLC
Whitney Rey
Official Correspondent
4135 S. Powder Rd., Suite 110
Mesa, Arizona 85212

Re: K210159
Trade/Device Name: IntraLock System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: June 23, 2021
Received: June 24, 2021

Dear Whitney Rey:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K210159

Device Name
IntraLock System™

Indications for Use *(Describe)*
IntraLock is indicated for reduction and internal fixation of arthrodesis, osteotomies, intra- and extra-articular fractures, and nonunions of the small bones and joints of the foot. The three-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 System

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

Date Prepared	06/23/2021
Submitted By	Fusion Orthopedics, LLC 4135 S. Power Rd., Suite 110 Mesa, AZ 85212 800-403-6876
Primary Contact	Whitney Rey 4135 S. Power Rd., Suite 110 Mesa, AZ 85212 800-403-6876 Tele e-mail: whitney@fusionorthopedics.com
Trade Name	IntraLock System
Common Name	Screw, Fixation, Bone
Classification Name	Smooth & threaded metallic bone fixation fasteners
Class	II
Product Code	HWC
CFR Section	21 CFR section 888.3040
Common Name	Screw, Fixation, Bone
Device Panel	Orthopedic
Primary Predicate Device	Fusion Orthopedics' IntraLock Lapidus System (K182342)
Secondary Predicate Device	Fusion Orthopedics' FuzeFix Screw System (K170038)
Device Description	The IntraLock System is a three-part construct, consisting of a Locking Lag Screw of 2 diameters and lengths ranging from 22mm to 55mm, a Setting Screw of 1 diameter with lengths ranging from 14mm to 24 mm, as well as a mating washer component consisting of 1 diameter and lengths ranging from 20mm to 28mm. The IntraLock Implants are constructed of titanium alloy (TI6Al4V). The specialized instruments are primarily made of surgical grade stainless steel (per ASTM F899) with certain components made from aluminum alloy (Al6061).
Indications for Use	The IntraLock System is indicated for reduction and internal fixation of arthrodeses, osteotomies, intra- and extra-articular fractures, and nonunions of the small bones and joints of 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 System and the predicate system are manufactured from the same material and process, with similar sized screws and are substantially equivalent in terms of intended use, design, mechanical safety and performance.
Non-clinical Test Summary	Both Static and Dynamic mechanical testing is presented to provided evidence that the IntraLock System is equivalent to that of the predicate. The sterilization, cleaning, packaging, material, and manufacturing methods are identical to that of the predicate.
Clinical Test Summary	No clinical studies were performed.
Conclusions:	Fusion Orthopedics LLC considers the IntraLock System to be equivalent to the predicate device listed above. This conclusion is based upon the devices' similarities in principles of operation, technology, materials and indications for use.