DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 20, 2017

Intrafuse LLC
Robert Hoy
Director of Research
124 South 600W, Suite 100
Logan, Utah 84321

Re: K163488
Trade/Device Name: Flex-Thread Clavicle Pin System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB, JDW
Dated: February 16, 2017
Received: February 17, 2017

Dear Mr. Hoy:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K163488

Device Name
Flex-Thread Clavicle Pin System

Indications for Use *(Describe)*
The Flex-Thread Clavicle Pin System is intended to be used to repair an acute fracture, mal-union or non-union of the clavicle.

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.

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5. 510(k) Summary

Device Trade Name: Flex-Thread Clavicle Pin System

Manufacturer:
IntraFuse LLC
124 South 600 West, Suite 100
Logan, UT 84321

Contact:
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Director of Research
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Prepared by:
Musculoskeletal Clinical Regulatory Advisers, LLC
1331 H Street NW, 12th Floor
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Phone: (202) 552-5800
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Date Prepared: December 12, 2016

Common Name:
Rod, fixation, intramedullary and accessories;
Pin, fixation, threaded

Classification: 21 CFR 888.3020, 21 CFR 888.3040

Class: II

Product Codes: HSB, JDW

Indications for Use:
The Flex-Thread Clavicle Pin System is intended to be used to repair an acute fracture, mal-union or non-union of the clavicle.

Device Description:
The Flex-Thread Clavicle Pin System is comprised of an intramedullary fixation device with a flexible threaded distal tip to engage the curved medial portion of a clavicle, and a proximal cross screw to further enhance stability and fixation to the lateral portion of the clavicle.

Predicate Devices:
The Synthes (USA) Elastic Intramedullary Nail (K971783, K053105, K042135, K081452, K082148), AOS Clavicle Intramedullary Device (K143204) and Sonoma

Orthopedic Products CRx Clavicle Fracture Repair Device (K081832, K100112) serve as the predicate devices.

Technological Characteristics Comparison:
The Flex-Thread Clavicle Pin System and its predicates are similar in design, function and size. Each device is designed to fix fractures from within the intramedullary canal. In addition, the subject and predicate device designs possess the ability to engage curved regions of the intramedullary canal. The CRx Clavicle Fracture Repair Device System, AOS Clavicle Intramedullary Device, and the subject device system contain cross screws as well.

The Flex-Thread Clavicle Pin System subject device implants and the Elastic Intramedullary Nail and CRx Clavicle Fracture Repair Device predicate device implants all contain stainless steel, a material with well-established biocompatibility and a long history of use in many previously cleared permanent implants. In addition the Flex-Thread Clavicle Pin implant contains polyetheretherketone (PEEK) conforming to ASTM F2026. The biocompatibility of this material has been established per ISO 10993-1. The mechanical testing demonstrates that the design differences between the Flex-Thread Clavicle Pin and the Elastic Intramedullary Nail introduce no new issues of safety or effectiveness.

Nonclinical Testing:
All necessary testing has been performed for the worst-case Flex-Thread Clavicle Pin and Cross Screw to assure substantial equivalence to its predicates and to demonstrate the subject device performs as intended. All testing was performed on test units representative of finished devices.

The Flex-Thread Clavicle Pin System performance was characterized through the following tests:

- Insertion & Removal Testing
- Static & Fatigue 4-Point Bending Testing
- Tensile Testing
- Torsion Testing
- Implant Tip Flexibility Testing

Clinical data were not needed to support the safety and effectiveness of the subject device.

Substantial Equivalence:
Side-by-side performance testing demonstrates the substantial equivalence of the Flex-Thread Clavicle Pin System to the Elastic Intramedullary Nail predicate device. The Flex-Thread Clavicle Pin System is substantially equivalent to the Elastic Intramedullary Nail (K971783, K053105, K042135, K081452, K082148), AOS Clavicle Intramedullary Device (K143204) and CRx Clavicle Fracture Repair Device (K081832, K100112) with respect to its indications for use, design, performance and function.