October 30, 2017

IntraFuse LLC
Robert Hoy
Director of Research
124 South 600 West, Suite 100
Logan, Utah 84321

Re: K172943
Trade/Device Name: Flex-Thread Fibula Pin System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary Fixation Rod
Regulatory Class: Class II
Product Code: HSB
Dated: September 22, 2017
Received: September 26, 2017

Dear Robert 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 (DICE) 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 (DICE) 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,

Mark N. Melkerson -S

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K172943

Device Name

Flex-Thread Fibula Pin System

Indications for Use *(Describe)*

The Flex-Thread Fibula Pin System is intended for use in the fixation of fibula fractures and osteotomies.

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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"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."

5. 510(k) Summary

Device Trade Name:	Flex-Thread Fibula Pin System
Manufacturer:	IntraFuse LLC 124 South 600 West, Suite 100 Logan, UT 84321
Contact:	Mr. Robert Hoy Director of Research Phone: (614) 448-6358 Fax: (435) 213-4878 bob@surgicalfrontiers.com
Prepared by:	Musculoskeletal Clinical Regulatory Advisers, LLC 1050 K Street NW, Suite 1000 Washington, DC 20001 Phone: (202) 552-5800 Fax: (202) 552-5798
Date Prepared:	September 22, 2017
Common Name:	Rod, fixation, intramedullary and accessories
Classification:	21 CFR 888.3020
Class:	II
Product Codes:	HSB

Indications for Use:
The Flex-Thread Fibula Pin System is intended for use in the fixation of fibula fractures and osteotomies.

Device Description:
The Flex-Thread Fibula Pin System is comprised of an intramedullary fixation device with a flexible threaded tip to engage the proximal portion of a Fibula, and cortical screws to further enhance stability and fixation of the Fibula.

Predicate Devices:
The Mahe Medical GmbH Mahe Fixation Plate and Screw System (K102845), the Sonoma Orthopedics Products, Inc. Sonoma Fibula Repair System (K142945, K160069) and the Acumed, LLC Acumed Small Bone IM Nail System (K143276, K071994, K031438) serve as the predicate devices.

Technological Characteristics Comparison:
The Flex-Thread Fibula Pin System and its predicates are similar in design, function and size. Each device is designed to fix fibular 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 beyond the fracture. The Sonoma Fibula Repair System, the Acumed Small Bone IM Nail System, and the subject device system all contain cortical screws as well.

The Flex-Thread Fibula Pin System subject device implants and the Acumed Small Bone IM Nail System predicate device implants are manufactured from titanium 6Al-4V ELI (ASTM F136), a material with well-established biocompatibility and a long history of use in many previously cleared permanent implants. The biocompatibility of the finished subject device implants and patient-contacting, device-specific instruments has been established per ISO 10993-1 and the relevant FDA guidance.

Nonclinical Testing:
All necessary testing has been performed for the worst-case Flex-Thread Fibula Pin 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 Fibula Pin System performance was characterized through the following tests:

- Insertion & Removal Testing
- Static & Fatigue 4-Point Bending 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 Fibula Pin System to the Mahe Fixation Screw predicate device. The Flex-Thread Fibula Pin System is substantially equivalent to the Mahe Medical GmbH Mahe Fixation Plate and Screw System (K102845), the Sonoma Orthopedics Products, Inc. Sonoma Fibula Repair System (K142945, K160069) and the Acumed, LLC Acumed Small Bone IM Nail System (K143276, K071994, K031438) with respect to its indications for use, design, performance and function.