510(k) SUMMARY - iFuse Implant System®

JUL 2 3 2014

510(k) Owner's Name, Address, and Telephone Number
SI-BONE, Inc., 3055 Olin Avenue, Suite 2200, San Jose, CA 95128
(408) 207-0700

Contact Person
Roxanne Dubois, VP, Regulatory and Quality, SI-BONE, Inc.
Email: rdubois@si-bone.com
Mobile: 408-828-5019
Office: 408-207-0700 x2236
Facsimile: 408-557-8312

Date Prepared: July 22, 2014

Trade Name of Device: iFuse Implant System®

Common or Usual Name: Orthopedic Rod

Classification Name: 21 C.F.R. 888.3040 – Smooth or threaded metallic bone fastener; Product Code OUR

Predicate Devices: iFuse Implant System by SI-BONE, Inc. (K080398, K092375, K110838, K122074, K123850 and K131405)

Intended Use
The iFuse Implant System is intended for sacroiliac joint fusion for conditions including sacroiliac joint dysfunction that is a direct result of sacroiliac joint disruptions and degenerative sacroiliitis.

Device Description
The iFuse Implant System consists of porous plasma spray coated titanium implants and associated surgical instruments. The iFuse Implant lengths range from 30-90mm with a diameter of 4-7mm. The fusion rods are implanted using instrumentation previously described in K080398, K092375, K110838, K122074, K123850 and K131405.

Technological Characteristics
The iFuse Implant System® consists of a series of metallic (titanium), porous plasma spray coated rods, intended for surgical implant within the bone to create biological fixation, immediate stabilization and fusion. This 510(k) does not involve any changes to the technological characteristics of the device.

Performance Data
No performance testing was required to support the modified labeling that is the subject of this 510(k).

Substantial Equivalence and Conclusion
The iFuse Implant System is substantially equivalent to the predicate device (iFuse Implant System).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 23, 2014

SI-BONE, Inc.
Ms. Roxanne Dubois
Vice President, Regulatory Affairs and Quality Assurance
3055 Olin Avenue, Suite 2200
San Jose, California 95128

Re: K141049
Trade/Device Name: iFuse Implant System®
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: OUR
Dated: July 8, 2014
Received: July 9, 2014

Dear Ms. Dubois:

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" (21CFR 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 yours,

Lori A. Wiggins

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K141049

Device Name: SI-BONE iFuse Implant System

Indications for Use:

The iFuse Implant System is intended for sacroiliac joint fusion for conditions including sacroiliac joint dysfunction that is a direct result of sacroiliac joint disruptions and degenerative sacroiliitis.

Prescription Use		Over-The-Counter Use
___X___ (Part 21 CFR 801 Subpart D)	AND/OR	_____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth L Frank -S

Division of Orthopedic Devices