INTELIFUSE
Fixation Using Smart Elements

510(K) SUMMARY (21 CFR 807.92)

INTELIFUSE, INC. WARMSYSTEM WITH STIMULINKS

510(k) Owner: InteliFUSE, Inc.
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Date Prepared: December, 2005

Trade Name: Warmsystem with StimuLinks

Common Name: Bone fixation staples

Classification Name: Bone fixation staples per 21 CFR 888.3030, JDR

Predicate Devices: Memograph Staple System with OSStaples
Warmsytem with StimuLinks

Device Description: The InteliFUSE, Inc. StimuLinks are shape memory alloy staples available in various sizes and guages appropriate for the fixation of bone to bone or soft tissue to bone. The staples have prongs which are parallel during insertion. Application of heat from the Warmsystem Console, or from the portable InteliFUSER warming devices results in compression and retention of the staples. Accessories to the System include instruments for locating drill holes, gauging hole depth, and inserting and tamping the staples in place.

Intended Use: The InteliFUSE, Inc, Warmsystem with StimuLinks is used as a system for the following indications:

1) hand and foot bone fragment and osteotomy fixation and joint arthrodesis.

2) fixation of proximal tibial metaphysis osteotomy.

3) fixation of soft tissue to bone such as anterior cruciate reconstruction.

4) fixation of maxillofacial and mandibulofacial fractures and osteotomies.

5) fixation of unloaded craniofacial bone fractures and craniostomies. The StimuLinks are contraindicated for craniofacial patients with a skull thickness less than the selected prong length.

6) adjunctive fixation of small bone fragments. These fragments may be located in long bones such as the femur, fibula and tibia in the lower extremities; the humerus, ulna or radius in the upper extremities; the clavicle and ribs; and in flat bones such as the pelvis, scapula and sternum

The indications are identical to those of the predicate device, the BioMedical Enterprises, Inc. Memograph System with OSStaples.

Technological Characteristics:

The Warmsystem Console applies an electrical current through two electrodes to the back of a Nitinol StimuLink to warm it above the transition temperature (45°C) causing the prongs to deflect inward. The console uses AC wall current stepped down via an electrical transformer. Heating is almost immediate. The Warmsystem is provided as a bench console or as one of two sterile hand held units, the InteliFUSER I (single battery) or the InteliFUSER II (dual battery). Both the console and portable devices apply heat using the same Joule effect. The user applies heat until the staple is transformed and the prongs deflect. This results in the compression across a fracture or fusion site during surgery.

Non-Clinical Performance Data:

Bench testing demonstrated that both the Warmsystem console and hand held units properly heat the StimuLinks until the staple is transformed and the prongs deflect. The Warmsystem console testing included electrical and mechanical safety when used for its intended purpose. The portable units are provided sterile using a validated ethylene oxide sterilization cycle, and a sterility assurance level (SAL) of 10^{-6} has been demonstrated. StimuLinks are radiation sterilized at a minimum dose validated to attain a

sterility assurance level (SAL) of 10^{-6}. StimuLinks meet the ISO 10993 standards for biocompatibility.

Clinical Data: Clinical testing was not required. The Warmsystem with StimuLinks is CE marked and the device is available in the US for hand and foot bone fragment and osteotomy fixation and joint arthrodesis, fixation of proximal tibial metaphysis osteotomy, and fixation of soft tissue to bone such as anterior cruciate reconstruction.

Conclusions: The non-clinical test results demonstrate that both the Warmsystem console and the hand held heating units supply the required degree of heat to transform the StimuLink staples.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 3 2006

InteliFUSE, Inc.
c/o Ms. Sharon Rockwell
President
Rockwell & Associates
5582 Chalon Road
Yorba Linda, California 92886

Re: K060014
Trade/Device Name: Warmsystem with StimuLinks
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Codes: JDR
Dated: March 15, 2006
Received: March 16, 2006

Dear Ms. Rockwell:

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.

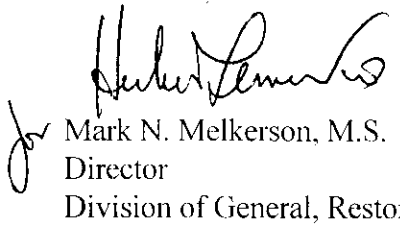
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson, M.S.
Director
Division of General, Restorative and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K060014

Device Name: InteliFUSE, Inc. Warmsystem with StimuLinks

The InteliFUSE, Inc. Warmsystem with StimuLinks is used as a system for the following indications:

1) hand and foot bone fragment and osteotomy fixation and joint arthrodesis.

2) fixation of proximal tibial metaphysis osteotomy.

3) fixation of soft tissue to bone such as anterior cruciate reconstruction.

4) fixation of maxillofacial and mandibulofacial fractures and osteotomies.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of General, Restorati
and Neurological Devices

510(k) Number K060014