JUN 2 9 2005

TAB 4

PREMARKET NOTIFICATION [510(K)] SUMMARY

March, 2005

Trade Name:	InteliFUSE, Inc. Warm System with StimuLinks
Common Name:	Bone Staple
Classification Name:	Staple, Bone Fixation (per 21 CFR section 888.3030)
Manufacturer's Name:	InteliFUSE, Inc. 5520 Willow Street New Orleans, LA 70115 504-864-8111
Corresponding Official:	Sharon Rockwell Regulatory Affairs Consultant 5582 Chalon Road Yorba Linda, CA 92886 Phone: (714) 695-9269 Fax: (714) 779-0406
Predicate Device(s):	Memograph Staple, Warm System, K993714, approved February 25, 2000 (for hand and foot bone fragment, osteotomy and fixation of soft tissue to bone)
Device Description:	The system consists of two and four prong staples for use in various fixation techniques. The Nitinol staples have prongs which are parallel during insertion. Application of heat from the Warm System to the staple causes the prongs to deflect inward. This inward deflection results in staple compression and retention. The heat is applied through two electrodes in an autoclavable heating wire. The electrodes are applied to the back of the implanted staple to activate heating.
Intended Use:	For bone to bone and soft tissue to bone fixation.
Technological Characteristics:	The Warm System uses the Joule effect of electrical current in a conductor to increase the temperature of the Nitinol staple. Internal circuitry controls the heating effect such that a limiting temperature of 55°C is achieved in a maximum of 5 seconds.

An accessory pack is provided with the Warm System and includes the resterilizable current source, drill bits of different sizes for creating proper hole diameters, a drill guide for depth gauging, an impactor for tapping the staples in place, forceps, and a locator pin. The accessory pack components are all commercially available finished devices.

The 2 prong StimuLink staples are available in wire thicknesses from 1.2 x 1.2 mm to 2mm x 3 mm, and in lengths and heights from 5 to 30 mm, including uneven prong heights. Four prong plates for multiaxial loads are available in ranges from 15 x 6 x 6 mm to 15 x 6 x 10 mm.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 9 2005

Ms. Sharon Rockwell
Regulatory Consultant
InteliFUSE Incorporated
5520 Willow Street
New Orleans, Louisiana 70115

Re: K051408
Trade/Device Name: InteliFUSE, Inc. Warm System with StimuLinks
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: JDR
Dated: May 27, 2005
Received: May 31, 2005

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,

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

TAB 3

INDICATIONS FOR USE

510(k) Number: K051408

Device Name: InteliFUSE, Inc. Warm System with StimuLinks

Indications for Use:

The InteliFUSE, Inc. Warm System with StimuLinks are 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.

☒ **Prescription Use** (per 21 CFR 801 Subpart D) or ☐ **Over-The-Counter Use** (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K051408