JUL 11 2014

Medical

510(K) SUMMARY

Owner's Name	William Rhoda
Submitter's Address	OT Medical 1000 Continental Drive, Suite 240 King of Prussia, PA 19034
Phone Number	(484) 588-2063
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510(k) Owner	OT Medical
Contact Person	William Rhoda, President & CEO
Date Prepared	June,10 2014
Trade Name	InstaFix™ Shape Memory Fixation System
Common Name	Staple, Fixation, Bone
Classification Name	Sec. 888.3030 Single/multiple component metallic bone fixation appliances and accessories
Section	Orthopedic
Product Code	JDR
Predicate Device	reVERTO™ Shape Memory Staples (K071477)
Device Description	InstaFix™ Shape Memory Fixation System is a set of dynamic compression implants made from shape memory metal nickel-titanium alloy called NiTinol. The staples are available in sizes 8mm to 30mm. The NiTinol construction causes the legs of the implant to deflect, thereby creating a compressive force across the site of fixation. InstaFix™ Shape Memory Fixation implants are advantageous to screws and plates in that they require less disruption of the surrounding bone for implantation and provide 'low-profile' fixation. The most important factor related to the use of NiTinol is its ability to maintain a compressive force across the site of fixation during the healing process. Each staple is packaged sterile along with the corresponding drill guide and implant holder. The one time use Accessory Kit and the Sizer Kit are packaged sterile to assist in the procedure. The Accessory Kit contains one drill and two locating pins. The Sizer Kit contains samples of the available staple sizes.
Reason for 510(k)	Modified device

Indications for Use	*InstaFix™ Shape Memory Fixation System* is intended for use in: Fixation of Osteotomies of the Hand, Foot and Tibia Arthrodesis of the Joints of the Hand and Foot Fixation of Soft Tissue to Bone, as in the case of the Anterior Cruciate Ligament *InstaFix™ Shape Memory Fixation System* is also indicated for adjunctive fixation of Small Bone Fragments of: The Upper Extremity, such as the Radius, Ulna, Humerus, Clavicle and Scapula The Lower Extremity, such as the Tibia, Fibula and the Femur The Upper Torso, such as the Sternum and the Ribs
Technological Characteristics	The InstaFix™ Shape Memory Fixation System implant is made of the same Nitinol material as the predicate. The implant is single use and sterilized by gamma radiation, which is the same as the predicate. The accessories are single use versus reusable. The staple sizes available are the same as the predicate. All patient contact components are made from biocompatible materials. This indicates that the components are safe for their intended use.
Substantial Equivalence	The InstaFix™ Shape Memory Fixation System is substantially equivalent in design, materials, intended use, indications for use, principles of operations and technological characteristics as the predicate reVERTO™ Shape Memory Staples K071477. There are differences in the packaging and the accessories are single use instead of reusable. The shelf life and sterilization method is the same. The risk analysis performed, raised no new issues of safety or efficacy.
Nonclinical Test Performed	The verification and validation testing of the InstaFix™ Shape Memory Fixation implant included staple fatigue life, pull-out fixation strength and elastic static bending. Design verification and validation testing included sterilization validation, packaging validation, sealing and aging study.
Conclusions Drawn	The substantial equivalence of the InstaFix™ Shape Memory Fixation System is based on the equivalence in intended use, materials, operational principals, technological characteristics and indications for use to reVERTO™ Shape Memory Staples K071477. Non-clinical testing demonstrates that the proposed device is safe, effective, and performs as well as the predicate device, therefore demonstrating substantial equivalence.

END OF 510(K) SUMMARY

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 11, 2014

OT Medical
Mr. William Rhoda
President & CEO
1000 Continental Drive, Suite 240
King of Prussia, Pennsylvania 19406

Re: K141550
Trade/Device Name: InstaFix™ Shape Memory Fixation System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: JDR
Dated: June 11, 2014
Received: June 12, 2014

Dear Mr. Rhoda:

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

Statement of Indications for Use

510 (K) NUMBER IF KNOWN: K141550

DEVICE NAME: InstaFix™ Shape Memory Fixation System

Indications for Use:

InstaFix™ Shape Memory Fixation System is intended for use in:

Fixation of Osteotomies of the Hand, Foot and Tibia

Arthrodesis of the Joints of the Hand and Foot

Fixation of Soft Tissue to Bone, as in the case of the Anterior Cruciate Ligament

InstaFix™ Shape Memory Fixation System is also indicated for adjunctive fixation of Small Bone Fragments of:

The Upper Extremity, such as the Radius, Ulna, Humerus, Clavicle and Scapula

The Lower Extremity, such as the Tibia, Fibula and the Femur

The Upper Torso, such as the Sternum and the Ribs

Prescription Use ☑ **AND/OR** **Over-the-Counter Use** ☐

(Part 21 CFR 801 Subpart D) (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)

Casey L. Hanley, Ph.D.

Division of Orthopedic Devices

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