(510(k) Summary)

K131640

Product: HammerLock

Submitter Information

BioMedical Enterprises, Inc.
14785 Omicron Drive, Ste. 205
San Antonio, Texas 78245

OCT 16 2013

Telephone: (210) 677-0354
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Contact: Joe W. Soward
Date Prepared: September 12, 2013

Classification name: Smooth or Threaded Metallic Bone Fastener (21 CFR 888.3040)

Classification:	Class II
Product Code:	HTY
Common/Usual Name:	Intramedullary Bone Fastener
Proprietary Name:	Hammerlock

Intended Use:

The Hammerlock is indicated for: Small bone reconstruction and fusion such as inter-digital fusion of fingers and toes.

Substantial Equivalence:

The upgraded Hammerlock is substantially equivalent to the predicate BME Hammerlock cleared in K091951.

Device Description

The Hammerlock is a nitinol implant that comes in a range of sizes to provide intramedullary fixation for fingers and toes. The Hammerlock

device is situated in the intramedullary space and the prongs extending into the cancellous bone. When the device is warmed by body temperature, the prongs deflect outward to create an anchoring force.

This configuration change for the Hammerlock involves minor configuration changes and adding new sizes to the product line for surgeon choice to better conform to patient anatomy.

Technological Characteristics Comparison to the Predicates:

Product Name:	Upgraded Hammerlock	Predicate Hammerlock (K091951)
Raw Material:	Nitinol, per ASTM F2063-05	Nitinol, per ASTM F2063-05
Sizes:	12,14,16,19,22 mm	16,19,22 mm
Styles:	Straight and 10 degree Angled	Straight
Pre-Operative Storage:	Must be frozen prior to use	Must be frozen prior to use
Heat Source:	Fully transformed at body temperature	Fully transformed at body temperature

Performance Bench Testing:

Standard ASTM F382-99 was used to compare the mechanical bend test parameters of the new Hammerlock to the predicate K091951 Hammerlock. The results showed that all of the new Hammerlock designs were substantially equivalent to the stiffness and strength of the predicate.

Standard ASTM F2129-08 was used to compare the corrosion resistance of representative samples of the new Hammerlock to technical literature and to predicate SmartToes devices (K070598). The test results demonstrate that the Hammerlock corrosion resistance is adequate according to technical literature and substantially equivalent to that of the SmartToe.

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

October 16, 2013

BioMedical Enterprises, Incorporated
Mr. Joe Soward
Director, Quality Assurance/Regulatory Affairs
14785 Omicron Drive, Suite 205
San Antonio, Texas 78245

Re: K131640
Trade/Device Name: HammerLock®
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HTY
Dated: September 19, 2013
Received: September 20, 2013

Dear Mr. Soward:

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

Erin D Keith

for

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

Enclosure

Indications for Use

510(k) Number (if known): K131640

Device Name: HammerLock®

Indications For Use: The HammerLock® is indicated for:
Small bone reconstruction and fusion such as inter-digital fusion of fingers and toes.

Prescription Use ✓ (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)

Casey L. Hanley, Ph.D.
Division of Orthopedic Devices