(510(k) Summary)

JAN - 9 2014

Product: HammerLock® 2

Submitter Information

BioMedical Enterprises, Inc.
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San Antonio, Texas 78245
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Contact: Joe W. Soward

Date Prepared: October 31, 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® 2

Intended Use:

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

Substantial Equivalence:

The HammerLock® 2 is substantially equivalent to the predicate BME HammerLock® cleared in K131640.

Device Description

The HammerLock® 2 is a nitinol implant that comes in a range of sizes to provide intramedullary fixation for fingers and toes. The HammerLock® 2 device is situated in the intramedullary space and the legs extend into the cancellous bone. After reaching body temperature, the legs fully deflect outward to create an anchoring force.

The changes for the HammerLock® 2 system involve design changes to the implant and new disposable instrumentation.

Technological Characteristics Comparison to the Predicates

Product Name:	HammerLock® 2 New device	Predicate HammerLock® (K131640)
Raw Material:	Nitinol, per ASTM F2063-05	Nitinol, per ASTM F2063-05
Sizes:	17, 20, 22, and 25 mm	12, 14, 16, 19, 22 mm
Styles:	Straight and 10 degree Angled	Straight and 10 degree angled
Pre-Operative Storage:	Room temperature	Must be frozen prior to use
Heat Source:	Fully transformed at body temperature	Fully transformed at body temperature

Implant Dimensions:

The new HammerLock® 2 device is longer than the predicate K131640 HammerLock®. The length is added to the proximal side of the implant (the portion designed to be inserted into the proximal phalanx). The extended proximal length of the HammerLock® 2 allows for better fixation.

Performance Bench Testing:
Standard ASTM F382-99 was used to compare the mechanical bending parameters of the new HammerLock® 2 to the predicate K131640 HammerLock®. The results showed that all of the new HammerLock® 2 designs exceed 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® 2 to technical literature and to predicate SmartToe devices (K070598). 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

January 9, 2014

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

Re: K133520
Trade/Device Name: HammerLock® 2
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HTY
Dated: November 7, 2013
Received: November 15, 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" (21 CFR 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,

Ronald P. Jean -S 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): K133520

Device Name: HammerLock® 2

Indications For Use:

The HammerLock® 2 is indicated for:
Small bone reconstruction and fusion such as inter-digital fusion of fingers and toes.

Prescription Use __X_ 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