(510(k) Summary)

MAY 1 4 2013

Product: Speed Shift™

Submitter Information

BioMedical Enterprises, Inc.
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Date Prepared: January 17, 2013

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

Classification:	Class II
Product Code:	JDR
Common/Usual Name:	Bone Staple
Proprietary Name:	Speed Shift™

Intended Use:

The Speed Shift™ is indicated for:
Fracture and osteotomy fixation and joint arthrodesis of the hand and foot.

Substantial Equivalence:

The Speed Shift™ is substantially equivalent to the predicate BME OSStaple™ cleared in K993714 and the OSStaple™ Chill cleared in K102107. The predicates also include an intended use of fixation of proximal tibial metaphysis osteotomy which is not included in this submission.

Device Description

The Speed Shift™ is a nitinol implant that comes in a range of sizes and models for use in extremity bone fragment fixation, osteotomy fixation, and joint arthrodesis. The implant is delivered to the operating room in an "open" martensitic state. The implant is then transformed by ambient and body heat after insertion, and contracts to a "closed" austenitic state. The implants do not require any external heating; they are completely transformed by body heat.

This configuration change for the Speed Shift™ consists of a step bend of the staple back where the bend is in line with the legs of the staple rather than perpendicular to the legs as in the predicate devices. This in line bend allows Speed Shift™ to be useful for step osteotomies such as in the calcaneal slide procedure and other various mid-foot procedures reducing the prominence of the staple back after implantation as compared to the predicate devices.

Technological Characteristics Comparison to the Predicates

Product Name:	Speed Shift™	Predicate OSStaple™ (K993714)	Predicate OSStaple Chill (K102107)
Raw Material:	Nitinol, per ASTM F2063-05	Nitinol, per ASTM F2063-05	Nitinol, per ASTM F2063-05
Bridge Lengths (mm):	15 and 20	9, 11, 13, 15, 18, 20, and 30	9, 11, 13, 15, 18, and 20
Leg Lengths (mm):	20	7, 8, 10, 12, 15, 18, 20, and 30	7, 8, 10, 12, 15, 18, and 20
Cross-section Dimensions (mm):	1.8 x 1.8 square	Min 1.2 x 1.2 Max 2.0 x 3.0	Min 1.2 x 1.2 Max 2.0 x 3.0
Barbs:	Barbs on the legs	Smooth legs	Barbs on the legs
Heat Source::	Fully transformed at room temperature	OSSforce™ electrical heating unit	Body temperature
Surface Finish:	Mechanical tumbling, acid cleaning, and chemical passivation.	Mechanical tumbling, acid cleaning, and chemical passivation.	Mechanical tumbling, acid cleaning, and chemical passivation.
Storage::	Sterile packaged stored at room temp until used.	Sterile packaged, stored at room temp until used.	Sterile packaged, and requires storage in freezer prior to use.

Performance Bench Testing:

Standard ASTM F564-10 (2010) was used to compare the pull-out strength of the new Speed Shift™ to the predicate OSStaple™. Specimens of the largest and smallest sizes of the Speed Shift™ were used and compared to a comparably sized predicate OSStaple™. The results showed that the Speed Shift™ has higher pull-out resistance than the predicate OSStaple™.

Standard ASTM F564-10 (2010) was used to compare the mechanical strength ™. The results showed that the Speed Shift™ achieve greater bending strength when compared to the predicate OSStaple™.

Standard ASTM F2129-08 was used to compare the corrosion resistance of representative samples of the new Speed Shift™ to the predicate OSStaple™. Test results demonstrate the corrosion resistance is equivalent to the predicate OSStaple Chill™.

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

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

Letter dated: May 14, 2013

Re: K124022
Trade/Device Name: Speed Shift™
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: JDR
Dated: April 12, 2013
Received: April 16, 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,

Mark N. Melkerson -S

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): K124022

Device Name: Speed Shift™

Indications For Use: The Speed Shift™ Fixation system is indicated for fracture and osteotomy fixation and joint arthrodesis of the hand and foot.

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