**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 17, 2014

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

Re: K142292
Trade/Device Name: Speed™, Speed Shift™, Speed Titan™, Speed Arc™
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: August 13, 2014
Received: August 19, 2014

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 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 -S

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

Enclosure

Device Name: Speed™, Speed Shift™, Speed Titan™ and Speed Arc™

**Indications for Use**

The Speed™, Speed Shift™, Speed Titan™ and Speed Arc™ are indicated for:

- Fracture and osteotomy fixation and joint arthrodesis of the hand and foot.
- Fixation of proximal tibial metaphysis osteotomy.
- Hand and foot bone fragment and osteotomy fixation and joint arthrodesis.
- Fixation of small bone fragments (i.e. small fragments of bone which are not comminuted to the extent to preclude staple placement). These fragments may be located in long bones such as the femur, fibula and tibia in the lower extremities; the humerus, ulna or radius in the upper extremities; the clavicle and ribs; and in flat bone such as the pelvis, scapula and sternum.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

BioMedical Enterprises

**(510(k) Summary)**

**Product: Speed™, Speed Shift™, Speed Titan™, Speed Arc™**

Submitter Information

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Contact: Joe W. Soward

Date Prepared: July 31, 2014

Classification name: Single/multiple component metallic bone fixation appliances and accessories (21 CFR 888.3030)

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

Intended Use:

The Speed™, Speed Shift™, Speed Titan™ and Speed Arc™ are indicated for:

- Fracture and osteotomy fixation and joint arthrodesis of the hand and foot.
- Fixation of proximal tibial metaphysis osteotomy.
- Hand and foot bone fragment and osteotomy fixation and joint arthrodesis.
- Fixation of small bone fragments (i.e. small fragments of bone which are not comminuted to the extent to preclude staple placement). These fragments may be located in long bones such as the femur, fibula and tibia in the lower extremities; the humerus, ulna or radius in the upper extremities; the clavicle and ribs; and in flat bone such as the pelvis, scapula and sternum.

Substantial Equivalence:

The Speed™ is substantially equivalent to primary predicate BME OSStaple™ cleared in K993714, and reference predicates BME OSStaple™ K001354, Speed Shift™ cleared in K124022, Speed Arc™ cleared in K133270, and Speed XL™ cleared in K133780.

The Speed Shift™ device is substantially equivalent to primary predicate BME OSStaple™ cleared in K993714, and reference predicates original Speed Shift™ cleared in K124022 and BME OSStaple™ cleared in K001354.

The Speed Arc™ device is substantially equivalent to primary predicate BME OSStaple™ cleared in K993714, and reference predicates original Speed Arc™ cleared in K133270 and BME OSStaple™ cleared in K001354.

The Speed Titan™ device is substantially equivalent to primary predicate BME OSStaple™ cleared in K993714, and reference predicates original Speed XL™ cleared in K133780 and BME OSStaple™ cleared in K001354.

Device Description

The Speed™ product family consists of nitinol staple implants offered in a range of sizes for bone fixation. The Speed™ product family consists of Speed™, Speed Shift™, Speed Arc™, and Speed Titan™ with the primary difference being the shape of the bridge. The bridges range from flat (Speed™ and Speed Titan™), arched (Speed Arc™), and stepped (Speed Shift™) to conform to patient and osteotomy anatomy.

All of the Speed™ implants are delivered to the operating room with the legs parallel in a constraining plastic inserter. The implant is then released from the inserter and transformed by ambient and body heat after insertion so that the legs converge. The implants do not require any external heating; they are completely transformed at typical operating room temperatures or body heat.

The difference between the Speed™ implant staples and the primary predicate implant staples are their heat activating temperature as well as bridge shape (stepped or curved). The predicate BME OSStaple™ requires an external heating unit to warm the staples and activate the compression function. The bundled implant staples are activated at typical operating room temperatures or body temperature, and provide active compression without an external heating requirement.

Performance Bench Testing:

Corrosion testing per ASTM F2129 “Standard Test Method for Conducting Cyclic Potentiodynamic Polarization Measurements to Determine the Corrosion Susceptibility of Small Implant Devices” was performed on the Speed™ implants. Test results of the Speed™ demonstrated good corrosion resistance.


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Pull-out testing per ASTM F564-10 "Standard Specification and Test Methods for Metallic Bone Staples" was performed on Speed™ implants. Results demonstrated superior pull out resistance to the predicate OSStaple™.

Transformation testing per ASTM F2082-06 "Standard Test Method for Determination of Transformation Temperature of Nickel-Titanium Shape Memory Alloys by Bend and Free Recovery Method" was performed on Speed™ implants. Test results showed substantially equivalent results to reference predicates.

Four-point static bend testing per ASTM F564-10 "Standard Specification and Test Methods for Metallic Bone Staples" was performed on Speed™ implants. Test results showed superior bend stiffness to the predicate OSStaple™.

Therefore the Speed™, Speed Shift™, Speed Arc™ and Speed Titan™ are as safe, effective and perform as well or better than predicate devices outlined within this submission.

MRI testing as listed below was performed on Speed™ implants. Results from the test are included in the Instructions for Use.

1. Magnetically induced displacement force (ASTM F2052).
2. Magnetically induced torque (ASTM F2213).
3. MR image artifact (ASTM F2119).
4. Radio frequency induced heating (ASTM F2182).


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