



August 11, 2016

Food and Drug Administration
10903 New Hampshire Avenue
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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

Re: K153573
Trade/Device Name: Coverge™
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: July 8, 2016
Received: July 11, 2016

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 Parts 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,

Vincent J. Devlin -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)

K153573

Device Name

Converge™

Indications for Use (Describe)

The Converge™ is indicated for fractures of various bones, including the clavicle, pelvis, scapula, long bones (humerus, radius, ulna, femur, tibia and fibula), and small bones such as metacarpals, metatarsals and phalanges.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(K) Summary

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807.92, this information serves as a Summary of Safety and Effectiveness for the use of the Converge™.

1. Submitted By: BioMedical Enterprises, Inc.
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- Date: August 9, 2016

- Contact Person: Joe Soward
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2. Proprietary Name: Converge™

- Common Name: Bone Plate and Screws

- Classification Name and Definition: 21 CFR 888.3030 – Single/multiple
component metallic bone fixation appliances
and accessories.

- 21 CFR 888.3040 – Smooth or threaded
metallic bone fixation fastener.

- Device Product Code, Device Panel: HRS – Orthopedic Devices
HWC – Orthopedic Devices

3. Primary Predicate: GPC Medical Bone Plates and Bone Screws
K092493

- Reference Device: Nitinol Compression Plating System™
K143023



4. Device Description:

The BME Converge™ consists of a sterile bone plate offered in various configurations and sterile titanium screws. The Converge™ is situated on two bones, across the fracture site, with titanium locking screws extending through the plate and cortex. The Converge™ is activated at room temperature upon release from retention brackets. In its final configuration, the plate actively provides continuous compression across the fusion site.

The Converge™ system contains plates and screws in similar shapes and sizes and manufactured from the same materials according to the same steps as the reference device, Nitinol Compression Plating System™ (NCP). However, the Converge™ includes the addition of K-wire and retention brackets (as opposed to NCP's restraining instrument). The configurations of the BME Converge™ system include Straight shaped implants. Additionally, the BME Converge has been MR tested and results indicate it is MR Conditional, whereas the BME Nitinol Compression Plating System has not undergone MR testing.

The main differences between the BME Converge™ and the primary predicate, GPC Medical Bone Plates and Bone Screws include the configurations and the material. The GPC Medical Bone Plates are made out of titanium whereas the BME Converge plates are made out of nitinol. The GPC Medical Bone Plate system is either a rectangular or "T" shaped implant with four to seven holes for screws, while the Converge plate system includes a straight shape. Additionally, results of MR testing conclude that BME's Converge™ may be listed as MR Conditional. It is unclear whether GPC Medical bone Fixation Plates and Screw System have undergone MR testing.

5. Intended Use

The Converge™ is indicated for fractures of various bones, including the clavicle, pelvis, scapula, long bones (humerus, radius, ulna, femur, tibia and fibula), and small bones such as metacarpals, metatarsals and phalanges.

6. Technological Characteristics Comparison

The Converge™ Nitinol Compression Plate system and primary predicate GPC Medical Bone Plate system share the same technological characteristics. More specifically, they share the same indications and intended use. The primary differences between the devices involve differences in geometry related to plate configuration and plate thickness, delivery method, and implant material, in that the Converge™ plate is made of nitinol and the GPC plate is made of titanium.



7. Substantial Equivalence – Non-Clinical Evidence

The Converge™ is substantially equivalent to primary predicate GPC Medical Bone Plates and Bone Screws cleared in K092493. That clearance also included the DHS/DCS Plate System, the designs and indications of which we do not claim substantial equivalence. In addition, the BME Converge™ is manufactured from the same materials using the same processes as FDA cleared reference device BME Nitinol Compression Plating System™ K143023.

BME conducted a series of tests to compare the submitted devices to the predicates. The testing included: Static bend, Dynamic bend, Post fatigue corrosion, Post fatigue nickel leaching, Corrosion, Galvanic corrosion, MRI compatibility, MRI RF heating simulation, Bone screw insertion and removal, Plate compression, Bone screw torsion, Bone screw pull-out and Bone screw corrosion resistance. The results demonstrate substantial equivalence to predicate device.

8. Substantial Equivalence – Clinical Evidence

Not Applicable

9. Substantial Equivalence – Conclusions

The design characteristics of the subject devices do not raise any new types of questions regarding safety or effectiveness. From the evidence submitted in this 510(k), the subject devices can be expected to perform at least as well as the predicate system and are substantially equivalent.