March 22, 2019

OsteoCentric Trauma
% Meredith May
Vice President
Empirical Consulting LLC
4628 Northpark Dr.
Colorado Springs, Colorado 80918

Re: K190430
Trade/Device Name: OsteoCentric Bone Plate and Screw System
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: February 21, 2019
Received: February 22, 2019

Dear Meredith May:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Shumaya Ali -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190430

Device Name

OsteoCentric Bone Plate and Screw System

Indications for Use *(Describe)*
The OsteoCentric Bone Plate and Screw is intended for fixation of fractures, osteotomies, and non-unions of the clavicle, scapula, olecranon, humerus, radius, ulna, pelvis, tibia, and fibula, including, but not limited to periarticular, and intraarticular fractures

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) SUMMARY

Submitter's Name:	OsteoCentric Trauma
Submitter's Address:	5113 Southwest Pkwy, Ste. 150 Austin, TX 78735
Submitter's Telephone:	800-969-0639
Contact Person:	Meredith L. May, MS Empirical Testing Corp. 719.337.7579
Date Summary was Prepared:	21-Feb-2019
Trade or Proprietary Name:	OsteoCentric Bone Plate and Screw System
Common or Usual Name:	Plate, Fixation, Bone Screw, Fixation, Bone
Classification:	Class II per 21 CFR §888.3030
Product Code:	HRS, HWC
Classification Panel:	Division of Orthopedic Devices

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The OsteoCentric Bone Plate and Screw System consists of implants and instruments designed for fixation to treat fractures, deformations, revisions and replantations of bones and bone fragments. The system features nineteen (19) types of plates and bone screws for fixation that are locking or non-locking, and a set of instruments to facilitate installation and removal of the implants. The plates have screw holes, which allow for attachment to the bones or bone fragments. The plates are fabricated from medical grade stainless steel (ASTM F138), and offered in various widths and lengths.

INDICATIONS FOR USE

The OsteoCentric Bone Plate and Screw is intended for fixation of fractures, osteotomies, and non-unions of the clavicle, scapula, olecranon, humerus, radius, ulna, pelvis, tibia, and fibula, including, but not limited to periarticular, and intraarticular fractures.

The indications for use for the OsteoCentric Bone Plate and Screw System are identical or similar to that of the predicate devices.

TECHNICAL CHARACTERISTICS

The OsteoCentric Bone Plate and Screw System is made from medical grade stainless steel that conforms to ASTM F138. The subject and predicate devices have nearly identical technological characteristics and the minor differences do not raise any new issues of safety and effectiveness. Specifically the following characteristics are identical between the subject and predicates:

- Indications for Use
- Materials of manufacture
- Principles of operation

The differences between the subject and the primary predicate include:

- The subject system is offered with both locking and non-locking plates and screws whereas the primary predicate system is only non-locking.
- The diameter range for screws increased from 2.0mm – 4.5mm previously cleared to 2.0mm – 5.0mm.

Predicate Devices

510k Number	Trade or Proprietary or Model Name	Manufacturer	
K152000	SMV Bone Plate and Screw System	SMV Scientific	Primary
K150981	SMV Scientific Bone Screws	SMV Scientific	Reference
K150188	SMV Scientific 4.5mm Bone Screws	SMV Scientific	Reference
K001945	Medial Distal Tibia Plates	Synthes (USA)	Reference
K011335	One-Third Tubular DCL Plate	Synthes (USA)	Reference
K020872	3.5mm Broad LC-DCP Plates	Synthes (USA)	Reference
K082807	3.5 and 4.5mm Locking Compression Plate System with Expanded Indications	Synthes (USA)	Reference
K010321	Modular Foot System – 2.7mm Module	Synthes (USA)	Reference
K092609	3.5mm and 4.5mm Curved Narrow and Broad Locking Compression Plates (LCP), Straight Compression, Straight Reconstruction Bone Plates	Synthes (USA)	Reference
K092889	Syntec Osteo-Plate and Screw Fixation	Syntec Scientific Corp.	Reference

PERFORMANCE TESTING SUMMARY

Per the described risk analysis in Section 9, the mechanical performance of the OsteoCentric Bone Plate and Screw System was established per K152000, K150981, and K150188. The addition of the proposed subject components introduced no new worst case conditions to those that were already tested per ASTM F543 and ASTM F382 and cleared. No performance testing was performed for this submission because substantial equivalence was already established in the previously clearances and an engineering analysis was performed to confirm that the addition of the proposed subject components introduced no new worst case conditions to those that were previously cleared.

CONCLUSION

The subject modified is very similar to previously cleared SMV Scientific Bone Plate and Screw System. The subject OsteoCentric Bone Plate and Screw System has similar intended uses, indications, technological characteristics, and principles of operation as the predicate devices. The modifications raise no new types of safety or effectiveness questions. The overall technology characteristics and mechanical performance data lead to the conclusion that the OsteoCentric Bone Plate and Screw System is substantially equivalent to the predicate devices.