May 4, 2020

OsteoCentric Extremities, LLC
% Meredith May
Director of Consulting
Empirical Testing Corp.
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K200259
Trade/Device Name: Headless Compression Screw System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: January 31, 2020
Received: February 3, 2020

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-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, M.P.H.
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020

Indications for Use

510(k) Number *(if known)*
K200259

Device Name
OsteoCentric Extremities Headless Compression Screw System

Indications for Use *(Describe)*

The Headless Compression Screw System Micro-2.8 screw fasteners are intended for fixation of fractures and non-unions of small bones and small bone arthrodesis. Examples include, but are not limited to scaphoid and other carpal fractures, metacarpal and phalangeal fusions, osteotomies, and bunionectomies.

The Headless Compression Screw System Mini-3.9 screw fasteners are intended for fixation of small bones and small bone fragments, such as fractures of the metatarsals, arthrodeses of the carpals and phalanges, steochondritis dissecans, and ligament fixation.

The screw fasteners are intended for single use only and may not be reused under any circumstances.

The system drills and guide wires are single use instruments.

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

Submitter's Name:	OsteoCentric Extremities, LLC
Submitter's Address:	5113 Southwest Parkway, Suite 150 Austin, TX 78735
Submitter's Telephone:	1-800-969-0639
Contact Person:	Meredith May, MS RAC Empirical Testing Corp. 719-337-7579 mmay@empiricaltech.com
Date Summary was Prepared:	31-Jan-2020
Trade or Proprietary Name:	Headless Compression Screw System
Common or Usual Name:	Smooth or Threaded Metallic Bone Fixation Fastener
Classification:	Class II per 21 CFR §888.3040
Product Code:	HWC
Classification Panel:	Division of Orthopedic Devices

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The OsteoCentric Extremities Headless Compression Screw System within the product line of SMV Scientific Cannulated Screws consists of cannulated screws in a variety of lengths and diameters to accommodate different anatomic sizes of patients. The screws are provided non-sterile. The subject headless compression screws are manufactured from Titanium per ASTM F136. The Headless Compression Screw System fasteners are offered in diameters of Ø2.8mm or Ø3.9mm and lengths from 12mm to 50mm.

INDICATIONS FOR USE

The Headless Compression Screw System Micro-2.8 screw fasteners are intended for fixation of fractures and non-unions of small bones and small bone arthrodesis. Examples include, but are not limited to scaphoid and other carpal fractures, metacarpal and phalangeal fusions, osteotomies, and bunionectomies.

The Headless Compression Screw System Mini-3.9 screw fasteners are intended for fixation of small bones and small bone fragments, such as fractures of the metatarsals, arthrodeses of the carpals and phalanges, steochondritis dissecans, and ligament fixation.

The screw fasteners are intended for single use only and may not be reused under any circumstances.

The system drills and guide wires are single use instruments.

The indications for use for the subject Headless Compression Screw System are the same to that of the previously cleared Cannulated Screws (K170021).

TECHNICAL CHARACTERISTICS

The OsteoCentric Extremities Headless Compression Screw System are made from titanium per ASTM F136. 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
- Sizes

Table 5-1 Predicate Devices

510k Number	**Trade or Proprietary or Model Name**	**Manufacturer**	**Predicate Type**
K170021	SMV Scientific Cannulated Screws	SMV Scientific	Primary
K081011	AREX SCRU2 Headless Compression Screws	AREX USA	Additional
K152000	SMV Bone Plate and Screw System	SMV Scientific	Reference

PERFORMANCE TESTING SUMMARY

In support of this Special 510(k) Device Modification Premarket Notification, OsteoCentric Extremities has conducted engineering analyses and geometric comparisons to demonstrate that the modifications to the subject Headless Compression Screw System introduce no new worst-case for mechanical testing compared to what was tested under K170021.

CONCLUSION

The subject OsteoCentric Extremities Headless Compression Screw System is very similar to previously cleared Cannulated Screws (K170021). The subject Headless Compression Screw System fasteners have 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 evaluation lead to the conclusion that the OsteoCentric Extremities Headless Compression Screw System is substantially equivalent to the predicate devices.