Advanced Orthopaedic Solutions
Elaine Nguyen
Regulatory Specialist
3203 Kashiwa Street
Torrance, California 90505

October 30, 2018

Re: K182466
Trade/Device Name: AOS Calcaneal Plating 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
Dated: September 7, 2018
Received: September 10, 2018

Dear Elaine Nguyen:

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,

Jesse Muir -S
2018.10.30 14:52:02 -04'00'

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)*

K182466

Device Name
AOS Calcaneal Plating System

Indications for Use *(Describe)*
The AOS Calcaneal Plating System is intended for fixation of fractures, osteotomies, nonunions, replantations, and fusions of small bones and small bone fragments, particularly in osteopenic bone.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

AOS
ADVANCED ORTHOPAEDIC SOLUTIONS

6. TRADITIONAL 510(K) SUMMARY

DATE PREPARED: September 7, 2018

SUBMITTED BY:
Advanced Orthopaedic Solutions, Inc.
3203 Kashiwa Street
Torrance, CA 90505
Phone: (310) 533-9966
Establishment Registration #: 2032480
Owner Operator Number: 9046896

CONTACT PERSON:
Elaine Nguyen
Regulatory Affairs Specialist
Advanced Orthopaedic Solutions, Inc.
3203 Kashiwa Street
Torrance, CA 90505
Phone: (310) 533-9966

DEVICE NAME: AOS Calcaneal Plate

COMMON NAME: Plate, Fixation, Bone

CLASSIFICATION: Class II, 21 CFR 888.3030 Single/multiple component metallic bone fixation appliances and accessories

DEVICE CODE: HRS

SUBSTANTIALLY EQUIVALENT DEVICES:
Synthes One-Third Tubular DCL Plate, K011335
Synthes (USA) Modular Mini Fragment LCP, K063049;
AOS Small Fragment Plate System Lite, K181035

DEVICE DESCRIPTION: The AOS Calcaneal Plating System consists of titanium plates in various configurations and sizes. The system is compatible with the AOS Small Fragment Plating System Instruments (K161913 cleared November 4^{h} 2016) and non-locking screws in diameters of 2.4mm, 2.7mm, 3.5mm, and 4.0mm. The system includes variable angle locking screws in diameter of 2.7 and 3.5mm. The plate system also includes 3.5mm headless compression screws, 4.0mm cannulated screws, and 4.0mm partially threaded cannulated screws.

[redacted]

INDICATIONS FOR USE:

The AOS Calcaneal Plating System is intended for fixation of fractures, osteotomies, nonunions, replantations, and fusions of small bones and small bone fragments, particularly in osteopenic bone.

SUBSTANTIAL EQUIVALENCE:

Information presented supports substantial equivalence of the AOS Calcaneal Plating System to the predicate devices. The proposed system has the same indications for use, is similar in shape and design, and has the same fundamental technology.

BASIS FOR SUBSTANTIAL EQUIVALENCE:

The AOS Calcaneal Plating System has the following similarities to the predicates:

- Same device classification
- Same cross sectional area
- Same thickness
- Same hole features

PRECLINICAL TESTING:

The AOS Calcaneal Plating System has the same indication, similar design, and same fundamental technology compared to the AOS Small Fragment Plating System Lite (K181035). A worst case sample with similar cross sectional area to the AOS Calcaneal Plating System was tested in comparative mechanical testing against the Synthes Modular Mini Fragment LCP System per a four-point bend test based on ASTM F382-17. The results demonstrate that the AOS Calcaneal Plating is substantially equivalent to the predicate.

An Engineering analysis was used to demonstrate the substantial equivalence to the AOS Small Fragment Plating System Lite.

STANDARDS:

Recognized industry standards are cited in the Standards Report

CLINICAL DATA:

There is no clinical data referenced in this 510(k)

PERFORMANCE TESTING:

No performance standards applicable to this device have been adopted under Section 514 of the Food, Drug and Cosmetic Act. Performance testing of the AOS Calcaneal Plating System was conducted in accordance with various international standards and internal AOS methods.

CONCLUSION:

Since the device has the same intended use and similar technological characteristics to the identified predicates, the device does not raise any different questions of safety or effectiveness. The

performance testing and engineering analysis demonstrated that the subject device had substantially equivalence performance. Therefore, the premarket notification demonstrated that the device is substantially equivalent to the predicate.