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 4, 2016

Advanced Orthopaedic Solutions, Inc. (AOS)
Alex Bhaskarla
Regulatory Affairs Manager
3203 Kashiwa Street
Torrance, California 90505

Re: K161913
Trade/Device Name: AOS Small Fragment 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, HWC, HTN
Dated: October 12, 2016
Received: October 14, 2016

Dear Mr. Bhaskarla:

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" (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 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,

Mark N. Melkerson -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161913

Device Name
AOS Small Fragment Plating System

Indications for Use *(Describe)*
The AOS Small Fragment Plating System is intended to be used for fixations of fractures, osteotomies, and non-unions of the clavicle, scapula, olecranon, humerus, radius, ulna, pelvis, distal tibia, fibula, 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.

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4. Special 510(K) SUMMARY

DATE PREPARED: June 13, 2015

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:
Alex Bhaskarla
Advanced Orthopaedic Solutions, Inc.
3203 Kashiwa Street
Torrance, CA 90505
Phone: (310) 533-9966

DEVICE NAME: AOS Small Fragment Plating System

COMMON NAME: Small Fragment Plate

CLASSIFICATION: Class II, 21 CFR 888.3030 Single/multiple component metallic bone fixation appliances and accessories and 21 CFR 888.3040 Smooth/threaded metallic bone fixation fastener.

No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for small fragment plates.

DEVICE CODE: HRS, HWC, HTN

SUBSTANTIALLY EQUIVALENT DEVICES: AOS Small Fragment Plating System (510k):K152732 Cleared December 10, 2015

DEVICE DESCRIPTION: The AOS Small Fragment Plating System consists of titanium plates, screws, and washers in various configurations and sizes. The system includes Kirschner wires, non-locking screws in diameters of 2.7mm, 3.5mm, and 4.0mm. The system includes variable angle locking screws in diameters of 2.7mm, and 3.5mm. The plate system includes 3.5mm headless compression screws, 4.0mm cannulated screws, and 4.0mm partially threaded cannulated screws.

INDICATIONS FOR USE: The AOS Small Fragment Plating System is intended to be used for fixations of fractures, osteotomies, and non-unions of the clavicle, scapula, olecranon, humerus, radius, ulna, pelvis, distal tibia, fibula, particularly in osteopenic bone.

SUBSTANTIAL EQUIVALENCE: Information presented supports substantial equivalence for modifications to the AOS Small Fragment 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.

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BASIS FOR SUBSTANTIAL EQUIVALENCE:

The modification to AOS Small Fragment Plating System has the following similarities to the AOS Small Fragment Plating System (K152732):

- same intended use
- same indications for use
- same raw material
- same method of manufacture
- same design
- similar sizes and dimensions
- same type of interface
- same shelf life
- same biocompatibility
- same sterilization
- same packing methods
- same physical limitations

The modified AOS Small Fragment Plating System has longer and shorter plates, shorter screws, and screw cannulation.

PRECLINICAL TESTING:

The AOS Small Fragment Plating System was subjected to comparative mechanical testing per a four point bend test based on ASTM F382-14. The results demonstrate that the AOS Small Fragment Plating System and accessories are substantially equivalent to the predicate.

STANDARDS:

Recognized industry standards are cited in the Standards Report

CLINICAL DATA:

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