



Food and Drug Administration  
10903 New Hampshire Avenue  
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Silver Spring, MD 20993-0002

Advanced Orthopaedic Solutions, Incorporated (AOS)  
Mr. Mark Steinhauer  
Product Development Engineer  
3203 Kashiwa Street  
Torrance, California 90505

December 10, 2015

Re: K152732

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 2, 2015  
Received: October 5, 2015

Dear Mr. Steinhauer:

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" (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 yours,

**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)  
K152732

Device Name  
AOS Small Fragment Plating System

*(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, including 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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**5. TRADITIONAL 510(K) SUMMARY**

**DATE PREPARED:** September 4, 2015

**SUBMITTED BY:** Advanced Orthopaedic Solutions, Inc.  
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Phone: (310) 533-9966

**CONTACT PERSON:** Mark Steinhauer  
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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.

**DEVICE CODE:** HRS, HWC and HTN

**SUBSTANTIALLY EQUIVALENT DEVICES:** Synthes Small Fragment Dynamic Compression Locking (DCL) System (510(k): K000684, Cleared April 28, 2000) and Synthes 2.7mm/3.5mm LCP Distal Fibula Plates (510(k): K073460, Cleared February 21, 2008).

**DEVICE DESCRIPTION:** The AOS Small Fragment Plating System consists of titanium plates in various configurations and sizes. The system includes non-locking and variable angle locking screws in diameters of 2.4mm, 2.7mm, 3.5mm, and 4.0mm. The plate system also includes 3.5mm headless compression 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, including osteopenic bone.

**SUBSTANTIAL EQUIVALENCE:** Information presented supports substantial equivalence of 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.

**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 and a Variable Angle Locking Mechanism test to evaluate the screw-plate interface. The results demonstrate that the AOS Small Fragment Plating System and accessories are substantially equivalent to the predicates.