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

August 24, 2018

Re: K181035
Trade/Device Name: AOS Small Fragment Plating System Lite
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: July 18, 2018
Received: July 24, 2018

Dear Alex 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. 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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181035

Device Name

AOS Small Fragment Plating System Lite

Indications for Use *(Describe)*

The AOS Small Fragment Plating System Lite is intended to be used for fixations of fractures, osteotomies, and non-unions of the clavicle, scapula, olecranon, humerus, radius, ulna, pelvis, distal tibia, and/or 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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ADVANCED ORTHOPAEDIC SOLUTIONS

6. TRADITIONAL 510(K) SUMMARY

DATE PREPARED: October 5, 2017 by Alex Bhaskarla

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

DEVICE NAME: AOS Small Fragment Plating System Lite

COMMON NAME: Plate, Fixation, Bone

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

DEVICE CODE: HRS

PREDICATE DEVICES:

Primary: Synthes One Third Tubular Plate K011335

Additional Predicates:

Small Fragment Dynamic Compression Locking (DCL) System K000684

AOS Small Fragment Plating System K161913

DEVICE DESCRIPTION:

The AOS Small Fragment Plating System Lite consists of titanium plates in various configurations and sizes. The system is compatible with the AOS Small Fragment Plating System Instruments and 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 Lite is intended to be used for fixations of fractures, osteotomies, and non-unions of the clavicle, scapula, olecranon, humerus, radius, ulna, pelvis, distal tibia, and/or fibula, including osteopenic bone.

TECHNOLOGY COMPARISON:

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

The AOS Small Fragment Plating System Lite has the following similarities to the predicate:

- Same device classification
- Same low profile feature
- Within length range of plates
- Within Diameter range of screws

Differences include hole configurations and width.

PRECLINICAL TESTING:

The AOS Small Fragment Plating System Lite device was found to have substantially equivalent bending strength and bending stiffness because of ASTM F382 Static and dynamic four-point bend testing and Engineering analysis.

An engineering analysis was used to demonstrate the subject screws have substantially equivalent performance in torsional strength, bending strength and axial pullout strength.

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 Small Fragment Plating System Lite plates 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 devcie does not raise any different questions of safety or effectivness. The performance testing and engineering analysis demonstrated that the subject device had substantially equivalent performance. Therefore, the premarket notification demonstrated that the device is substantially equivalent to the predicate.