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

Advanced Orthopaedic Solutions, Incorporated June 22, 2017
Mr. Alex Bhaskarla
Regulatory Affairs Manager
3203 Kashiwa Street
Torrance, California 90505

Re: K171606
Trade/Device Name: AOS Anterolateral Proximal Humeral Plate
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: KTW
Dated: June 1, 2017
Received: June 1, 2017

Dear Mr. 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. 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)*
K171606

Device Name
AOS Anterolateral Proximal Humeral Plate

Indications for Use *(Describe)*
The AOS Anterolateral Proximal Humeral Plate is indicated for fractures, fracture dislocations, osteotomies, and non-unions of the proximal humerus

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.

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Section 5 Special 510(k) Summary

DATE PREPARED:	May 22, 2017
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 Anterolateral Proximal Humeral Plate
COMMON NAME:	Appliance, Fixation, Nail/Blade/Plate Combination, Single Component
CLASSIFICATION:	Class II, 21 CFR 888.3030 Single/multiple component metallic bone fixation appliances and accessories
DEVICE CODE:	KTW
SUBSTANTIALLY EQUIVALENT DEVICES:	**Primary:** AOS Anterolateral Proximal Humeral Plate (510k): K160409 Cleared March 15, 2016 **Secondary:** Synthes (USA) LCP Proximal Humerus Plates (Philos), Long (510k): K041860 Cleared September 8, 2004
DEVICE DESCRIPTION:	The AOS Anterolateral Proximal Humeral plates are open reduction internal fixation devices for the temporary fixation of various types of fractures of the humerus and are intended as load sharing devices which may be removed once the fracture has healed. The AOS Anterolateral Proximal Humeral System consists of titanium plates, and proximal and distal locking and non-locking screws. 16 and 18 hole plates are being added to the system. The 16 hole plates are 9.4 inches long. The 18 hole plates are 10.4 inches long.
INDICATIONS FOR USE:	The AOS Anterolateral Proximal Humeral Plate is indicated for fractures, fracture dislocations, osteotomies, and non-unions of the proximal humerus.

Section 5 Special 510(k) Summary continued

PREDICATE COMPARISON: The AOS Anterolateral Proximal Humeral 16 and 18 hole plates have the following similarities to the predicates:

- same device classification
- same material
- same anatomical sites
- same intended use
- same biocompatibility
- same shaft width
- same locking screw hole diameters

SUBSTANTIAL EQUIVALENCE: The proposed system has the same indications for use, is similar in shape and design, and has the same fundamental technology. Information presented supports substantial equivalence for modifications to the AOS Anterolateral Proximal Humeral Plate to the predicate devices.

PRECLINICAL TESTING: The 16 and 18 hole plate additions to the Anterolateral Proximal Humeral Plate System do not present any decreases in strength, increases in risk, or additional safety risks thus mechanical testing is not necessary.

STANDARDS: Recognized industry standards are cited in the Standards Report.

CLINICAL DATA: There is no clinical data referenced in this special 510(k).