DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Advanced Orthopaedic Solutions, Incorporated
Kazu Miyahara
Product Development Engineer
3203 Kashiwa Street
Torrance, California 90505

March 15, 2016

Re: K160409
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: February 16, 2016
Received: February 17, 2016

Dear Kazu Miyahara:

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 Parts 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)*
K160409

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.

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ADVANCED ORTHOPAEDIC SOLUTIONS

8. SPECIAL 510(K) SUMMARY

SUMMARY PREPARED ON:	March 9, 2016
SUBMITTED BY:	Advanced Orthopaedic Solutions, Inc. 3203 Kashiwa Street Torrance, CA 90505 Phone: (310) 533-9966
CONTACT PERSON:	**Kazu Miyahara** 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 DEVICE:	AOS Proximal Humeral Plate (K080590, May 6, 2008)
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.
INDICATIONS FOR USE:	The AOS Anterolateral Proximal Humeral Plate is indicated for fractures, fracture dislocations, osteotomies, and non-unions of the proximal humerus.
SUBSTANTIAL EQUIVALENCE:	Information presented supports substantial equivalence of the Anterolateral Proximal Humeral plate to the predicate device. The proposed plates have the same indications for use, are similar in geometry and design, have the same fundamental

scientific technology, and are made of the same material (Ti-6Al-4V, per ASTM F1472) as the predicate plates. As detailed in the submission, the proposed plates do not present a worst-case scenario with respect to strength characteristics and because of their similarity to the current plates, physical testing was deemed unnecessary, and substantial equivalence was determined in strength and geometry between the proposed plates and predicate plates.