AOS

ADVANCED ORTHOPAEDIC SOLUTIONS

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OCT 24 2011

5. TRADITIONAL 510(K) SUMMARY

DATE PREPARED:	October 7, 2011
SUBMITTED BY:	Advanced Orthopaedic Solutions, Inc. 386 Beech Avenue, Unit B6 Torrance, CA 90501 Phone: (310) 533-9966
CONTACT PERSON:	Julie Glendrange Advanced Orthopaedic Solutions, Inc. 386 Beech Avenue, Unit B6 Torrance, CA 90501 Phone: (310) 533-9966
DEVICE NAME:	AOS Clavicle Plate System
COMMON NAME:	Internal Fixation
CLASSIFICATION:	Class II, 21 CFR 888.3030 Single/multiple component metallic bone fixation appliances and accessories.
DEVICE CODE:	HRS
SECONDARY DEVICE CODE:	HWC
SUBSTANTIALLY EQUIVALENT DEVICE:	Acumed® Congruent Bone Plate System, Clavicle Plate (510(k)s: K012655, Cleared Nov. 7, 2001; K063460, Cleared Dec. 7, 2006; and K071715, Cleared July 18, 2007.) Synthes® 3.5mm LCP Reconstruction Plate (510(k): K000684, Cleared April 28, 2000)
DEVICE DESCRIPTION:	The AOS Clavicle Plate system consists of bone plates and screws for fractures, fusions, and osteotomies of the clavicle bone. The bone plates are pre-shaped to fit the curves and angles of the clavicle and are provided in small, medium and large sizes. The plate accepts both locking and nonlocking screws.
INDICATIONS FOR USE:	The AOS Clavicle Plate System provides fixation for fractures, fusions, or osteotomies for the clavicle.
SUBSTANTIAL EQUIVALENCE:	Information presented supports substantial equivalence of the AOS Clavicle Plate System to the predicate device. The proposed plate has the same

indications for use, is similar in shape and design, and has the same fundamental technology.

PRECLINICAL TESTING:

The AOS Clavicle System was subjected to static and dynamic 4-point bend testing in accordance with ASTM F382, Standard Specification and Test Method for Metallic Bone Plates. The results demonstrate that the subject device is substantially equivalent to the predicates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

OCT 2 4 2011

Advanced Orthopaedic Solutions, Inc.
% Julie Glendrange
386 Beech Avenue, Unit B6
Torrance, CA 90501

Re: K103513
Trade/Device Name: AOS Clavicle Plate System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliance and accessories
Regulatory Class: II
Product Code: HRS/HWC
Dated: October 7th, 2011
Received: October 11th, 2011

Dear Ms. Glendrange:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

AOS

ADVANCED ORTHOPAEDIC SOLUTIONS

4. INDICATIONS FOR USE STATEMENT

Traditional 510(k) Premarket Notification
Indication for Use Statement
AOS Clavicle Plate System

510(k) Number (if known): K103513

Device Name: AOS Clavicle Plate System

Indications for Use:

The AOS Clavicle Plate System provides fixation for fractures, fusions, or osteotomies for the clavicle.

Prescription Use: X AND/OR Over-The-Counter Use: ____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Michael Owen for MCM

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K103513