AOS

ADVANCED ORTHOPAEDIC SOLUTIONS

SEP 26 2012

8. SPECIAL 510(K) SUMMARY

SUMMARY PREPARED ON: August 27, 2012

SUBMITTED BY:
Advanced Orthopaedic Solutions, Inc.
386 Beech Avenue, Unit B6
Torrance, CA 90501
Phone: (310) 533-9966

CONTACT PERSON:
Allyson Parks
Advanced Orthopaedic Solutions, Inc.
386 Beech Avenue, Unit B6
Torrance, CA 90501
Phone: (310) 533-9966

DEVICE NAME: AOS Short Clavicle Plates
COMMON NAME: Internal Fixation
CLASSIFICATION: Class II, 21 CFR 888.3030 Single/multiple component metallic bone fixation appliances and accessories

DEVICE CODE: HRS

SUBSTANTIALLY EQUIVALENT DEVICE: AOS Clavicle Plate System (K103513, October 24, 2011)

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 a range of curvatures and sizes. The plates accept both locking and non-locking screws.

The proposed new plates are shorter versions of the lateral and midshaft plates currently in the system. The 6 Hole Medium Midshaft Superior Clavicle Plate and 6 Hole Straight Midshaft Superior Clavicle Plate both come in right and left versions and follow the same basic curvature as that of the existing 8 Hole Medium and Straight Midshaft Clavicle Plates, respectively. The Short Lateral Superior Clavicle Plates come in right and left versions and follow the same basic geometry as the current lateral superior plates, with the addition of an elongated hole. The

elongated hole will be used for provisional placement with the ability to adjust the plate positioning.

All plates except for the short lateral plates have at least one bending notch. This notch feature is used for fine adjustment of the plate geometry in order to fit the plate more intimately with the bone surface.

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 Short Clavicle Plates 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 ELI, per ASTM F136) 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 the predicate plates.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

SEP 26 2012

Advanced Orthopaedic Solutions, Incorporated
% Ms. Allyson Parks
Regulatory Associate
386 Beech Avenue, Unit B6
Torrance, California 90501

Re: K122623
Trade/Device Name: AOS Short Clavicle Plates
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS
Dated: August 27, 2012
Received: August 28, 2012

Dear Ms. Parks:

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,

for

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

7. INDICATIONS FOR USE STATEMENT

Special 510(k) Premarket Notification
Indication for Use Statement
AOS Short Clavicle Plates

510(k) Number (if known): K122623

Device Name: AOS Short Clavicle Plates

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)

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

510(k) Number K122623