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AOS

ADVANCED ORTHOPAEDIC SOLUTIONS

MAY - 6 2008

510(k) SUMMARY

SUBBMITTED BY:	Advanced Orthopaedic Solutions 2444 205TH Street, Unit 5 Torrance, CA 90501 (310) 533-9966 FAX (310) 533-9876
510(k) CONTACT PERSON:	Paul Doner, Vice President Operations
TRADE NAME:	AOS Proximal Humeral Plate
COMMON NAME:	External Fixation
CLASSIFICATION:	21 CFR 888.3030 Single/multiple component metallic bone fixation appliances and accessories.
DEVICE CODE:	KTW
SUBSTANTIALLY EQUIVALENT DEVICE:	Synthes LCP Proximal Humeral Plate (K011815 and K04186)

DEVICE DESCRIPTION AND SUBSTANTIAL EQUIVALENCE RATIONALES:

The AOS Proximal Humeral Plate is an internal fixation device for the fixation of fractures of the humeral head and is intended as a load sharing device which may be removed once the fracture has healed.

The plate is manufactured in multiple lengths with the overall length of the plate ranging from 97mm to 236mm. The proximal portion has eight 135° angled holes to accept 4.0mm locking screw. The distal portion has 3, 5, 8, 11 and 14 hole configurations which will accept a 4.0mm locking screw or a 3.5mm cortical screw. There are three associated screws for the AOS Proximal Humeral Plate; the 4.0mm fully threaded locking screws, the 4.0mm partially threaded locking screw and the 3.5mm cortical screw. The AOS Proximal Humeral Plates and screws are manufactured from titanium alloy.

The overall length of the AOS Proximal Humeral Plate ranges from 97mm to 236mm while the proximal portion is consistent for all plates at 48mm. The proximal portion of the plate contains 8 threaded holes that accept the 4.0mm partially threaded cancellous locking screw. The proximal portion of the plate also contains six suture holes and a 2.0mm hole for positioning.

The distal shaft of the plate is manufactured in 3, 5, 8, 11 and 14 hole configurations with the first hole being a slot. These threaded holes are staggered through the length of the

plate and accept a 4.0mm fully threaded cancellous locking screw or the 3.5mm cortical screw.

SUBSTANTIAL EQUIVALENCE INFORMATION:

The AOS Proximal Humeral Plate and the predicate Synthes (USA) Proximal Humeral Plate have the same indication for use, similar design geometry and are manufactured from similar material. Therefore, mechanical testing to support Substantial Equivalence was not necessary.

Both the AOS Proximal Humeral Plate and the predicated Synthes Proximal Humeral Plate are indicated for: "fractures and fracture dislocations, osteotomies, and nonunions of the proximal humerus."

For both systems there are screws with a threaded head configuration which are specifically designed to lock into the plate. The screws used in the two systems are also of similar configuration in thread form and major and minor thread diameter.

The screws used in the system were not mechanically tested because they are of similar major and minor diameter. The 3.5mm is already cleared for use in the AOS Humeral Nail (K050241).

As the AOS Proximal Humeral Plate and the predicated device have similar design geometry, are manufactured from similar material and have the same indication it was determined that mechanical testing was not necessary to support substantial equivalence.

INTENDED USE:

AOS Proximal Humeral Plate is indicated for fractures and fracture dislocations, osteotomies, and nonunions of the proximal humerus.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Advanced Orthopaedic Solutions
% Mr. Paul Doner
Vice President Operations
2444 205th Street, Unit 5
Torrance, CA 90501

MAY - 6 2008

Re: K080590
Trade/Device Name: AOS 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 29, 2008
Received: March 3, 2008

Dear Mr. Doner:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Premarket Notification
Indication for Use Statement

510(k) Number (if known): K080590 (pg 1/1)

Device Name: AOS Proximal Humeral Plate

Indications for Use:

The AOS Proximal Humeral Plate is indicated for fractures, fracture dislocations, osteotomies, and non-unions of the proximal humerus.

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)

Neil R.P. Ogden for mkm

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K080590