JUN 2 0 2002

page 1 of 1
K01008

510(k) SUMMARY

NAME OF FIRM:	Advanced Orthopaedic Solutions
510(k) CONTACT PERSON:	Paul Doner Vice President Operations and Regulatory
TRADE NAME:	AOS Trochanteric Nail
COMMON NAME:	Intramedullary Fixation Rod
CLASSIFICATION:	888.3020 Intramedullary Fixation Rod.
DEVICE CODE:	HSB
SUBSTANTIALLY EQUIVALENT DEVICE:	DePuy Ace, Trochanteric Nail & Long Trochanteric Nail; Howmedica, Gamma Nail & Trochanteric Dyax Nail; Smith and Nephew, Intramedullary Hip Screw

INTENDED USE:
The AOS Trochanteric Nail is intended to treat stable and unstable proximal fractures of the femur including pertrochanteric, intertrochanteric and high subtrochanteric fractures and combinations of these fractures. The long trochanteric nail is additionally indicated for subtrochanteric fractures, pertochanteric fractures associated with shaft fractures, pathologic fractures (including prophylactic use) in osteoporotic bone of the trochanteric and diaphyseal areas, long subtrochanteric fracture, ipsilateral femoral fractures, proximal and distal non-unions and malunions and revisions procedures.

DEVICE DESCRIPTION AND SUBSTANTIAL EQUIVALENCE RATIONALES:
The AOS Trochanteric Nail is femoral intramedullary nail that is design to enter through the greater trochanter. It consists of an intramedullary nail, sliding lag screw, anti-rotation screw, locking screws and end cap.

The Trochanteric Nail is a cannulated nail with proximal bend and a proximal diameter of 15mm. The short Trochanteric Nails are18cm and 23cm in length and the long Trochanteric Nails are 30cm, 36cm and 42cm in length. The nails are produced in diameters of 9mm, and 11mm. The proximal end of the nail has two holes; one to accept the 11mm lag screw and one to accept the optional 5.0mm anti-rotation screw. There are two nail configurations with the proximal holes angled at 125° or 130°. The proximal holes in the long nails having 10° of anteversion and are in a left and a right configuration. The proximal end of the nail is threaded to accept an end cap.

The distal end of the nail contains one cross locking hole and one cross locking slot. The distal hole and the slot are design to accept 5.0mm screws.

The AOS Trochanteric Nail was shown to be substantially equivalent to the following devices.

DePuy ACE, Trochanteric Nails	K010780 and K013563
Howmedica Osteonics, Gamma Nails	K993670, K012158 and K013524
Smith and Nephew, Intramedullary Hip Screw	K 912162, K921786 and K954712

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 0 2002

Mr. Paul Doner
Vice President Operations and Regulatory
Advanced Orthopaedic Solotions
333 W. 6th Street, Suite 202
San Pedro, CA 90731

Re: K021008
Trade/Device Name: Advanced Orthopaedic Solutions Trochanteric Nail
Regulatory Number: 888.3020
Regulatory Name: Intramedullary fixation rod
Regulatory Class: II
Product Code: HSB
Dated: March 27, 2002
Received: March 28, 2002

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Milhem

Celia Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known) K021008 page 1 of 1

Device Name: **Advanced Orthopaedic Solutions Trochanteric Nail**

Indications for Use:

The AOS Trochanteric Nail is intended to treat stable and unstable proximal fractures of the femur including pertrochanteric, intertrochanteric and high subtrochanteric fractures and combinations of these fractures. The long trochanteric nail is additionally indicated for subtrochanteric fractures, pertochanteric fractures associated with shaft fractures, pathologic fractures (including prophylactic use) in osteoporotic bone of the trochanteric and diaphyseal areas, long subtrochanteric fracture, ipsilateral femoral fractures, proximal and distal non-unions and malunions and revisions procedures.

Concurrence of CDRH, Office of Device Evaluation

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter _____

for Mark N Milhous
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K021008