K014185 1/1

510(k) SUMMARY

FEB 1 3 2002

NAME OF FIRM:	Advanced Orthopaedic Solutions
510(k) CONTACT PERSON:	Paul Doner Vice President Operations and Regulatory
TRADE NAME:	AOS Cannulated Bone Screw System
COMMON NAME:	Bone Fixation Screws and Washers
CLASSIFICATION:	888.3040 Smooth or Threaded Metallic Bone Fixation Fastener 888.3030 Single/Multiple Bone Fixation Appliance and Accessories
DEVICE CODE:	HWC and HTN
SUBSTANTIALLY EQUIVALENT DEVICES:	Smith and Nephew - 5.5mm and 7.0mm Titanium and Stainless Steel Cannulated Screws Smith and Nephew - 6.5mm and 4.0mm Cannulated Screws Howmedica Osteonics – ASNIS III Cannulated Screw System

INTENDED USE:

The AOS Cannulated Bone Screw System is intended for fracture fixation of small and long bones and of the pelvis. This system is not intended for spinal use.

DEVICE DESCRIPTION AND SUBSTANTIAL EQUIVALENCE RATIONALES:

The AOS Cannulated Bone Screw System consists of titanium alloy self-drilling, self-tapping cannulated screws in diameters of 4.0mm, 5.0mm and 7.0mm and in lengths ranging from 10mm to 150mm. The screws are either partial threaded or fully threaded. There are two washers in the system, one for use with the 4.0mm and 5.0mm screws and one for use with the 7.0mm screws. All screw are packaged and sold as non-sterile.

The AOS Cannulated Bone Screw System is substantially equivalent to the following marketed devices: Howmedica Osteonics, ASNIS III Cannulated Screw System, 4.0mm, 5.0mm, 6.5mm and 8.0mm; Smith and Nephew, 5.0mm and 7.0mm Titanium and Stainless Steel Cannulated Screws; and the Smith and Nephew, 6.5mm and 4.0mm Cannulated Screws.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 3 2002

Mr. Paul Doner
Vice President, Operations and Regulatory
Advanced Orthopaedic Solutions (AOS)
333 W. 6th Street, Suite 202
San Pedro, California 90731

Re: K014185
Trade/Device Name: AOS Cannulated Bone Screw System
Regulatory Number: 888.3040 and 888.3030
Regulation Name: Smooth or Threaded Metallic bone Fixation Fastener and Single/Multiple bone Fixation Appliance and Accessories
Regulatory Class: II
Product Code: HWC and HTN
Dated: December 18, 2001
Received: December 20, 2001

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,

Miriam C. Provost
for Celia M. 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) K014185

Device Name: **AOS Cannulated Bone Screw System**

Indications for Use:

The AOS Cannulated Bone Screw System is intended for fracture fixation of small and long bones and of the pelvis. This system is not intended for spinal use.

Concurrence of CDRH, Office of Device Evaluation

Prescription Use X **OR** Over-The-Counter _____
(Per 21 CFR 801.109)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K014185