4/29/99

K990596

510 (k) Summary

Summary of 510 (k) safety and effectiveness information upon which the substantial equivalence determination is based:

Prepared: February 4, 1999

Applicant: Avanta Orthopaedics, Inc.
9369 Carroll Park Drive, Suite A
San Diego, CA 92121

Telephone: 619-452-8580
Fax: 619-452-9945
Contact: Louise M. Focht

Device Name:	Single/Multiple Component Metallic Bone Fixation Appliance and Accessories
Device Trade Name:	Distal Radius Fracture Fixation Plate System
Device Classification:	Class II
Reviewing Panel:	Orthopaedic
Regulation Number	888.3030
Product Code: Accessories	87HRS
Predicate Device:	Orthomet K943853 Synthes K953644 Avanta K981715

Device Description:

The distal radius plate like the predicate device includes various size plates, right, left, small, large, accessories and instruments. The bone screws enable the plate to be coupled to bone by securing the screws for the intended use. The various components within the system are provided to accommodate various anatomies and injuries.

Intended Use:

The intended use of the distal radius fracture fixation plate system is internal fixation of fractures and osteotomies of the distal radius. This may include:

- Displaced or non-displaced fracture which may or may not involve angulation or fragmentation of bone,
- Failed fracture fixation with or without bone graft,
- Osteotomy and repair of distal radius malunion with or without bone graft.

Comparison to Predicate Device:

The table below summarizes similarities and differences between the Orthomet, Synthes and the Avanta Orthopaedics devices.

Feature	Orthomet	Synthes	Avanta Orthopaedics
Plates	Implantable	Implantable	Implantable
Screws	Implantable	Implantable	Implantable
Material	316L	316L	316L

Summary:

The device and the predicate device have similar design characteristics and intended use. The new device is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 29 1999

Ms. Louise M. Focht
Director of Operations
Avanta Orthopaedics, Inc.
9369A Carroll Park Drive
San Diego, California 92121

Re: K990596
Trade Name: Distal Radius Fracture Fixation Plate System
Regulatory Class: II
Product Codes: HRS and HWC
Dated: February 4, 1999
Received: February 24, 1999

Dear Ms. Focht:

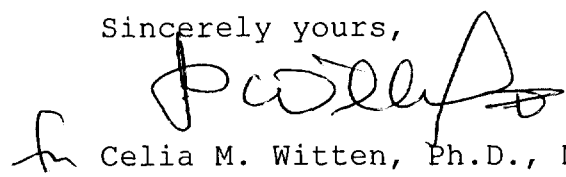
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



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

Enclosure

Indications for Use:

510(k) Number: K990596

Device Name: **Distal Radius Fracture Fixation Plate**

The intended use of the distal radius fracture fixation plate system is internal fixation of fractures and osteotomies of the distal radius. This may include:

- Displaced or non-displaced fracture which may or may not involve angulation or fragmentation of bone,
- Failed fracture fixation with or without bone graft,
- Osteotomy and repair of distal radius malunion with or without bone graft.

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K990596

Prescription Use X
(Per 21 CFR 801.109)