APR 1 0 2003

K030881

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510 (k) Summary

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

Prepared:	March 19, 2003
Applicant:	Avanta Orthopaedics, Inc. 9369 Carroll Park Drive, Suite A San Diego, CA 92121
Contact:	H. Doug Plunkett Avanta Orthopaedics, Inc. 8600 Evergreen Blvd. Minneapolis, MN 55433
Telephone: Fax: Email	763-783-5017 763-783-5073 dplunkett@machine.com

Device Name:	Single/Multiple Component Metallic Bone Fixation Appliance and Accessories
Device Trade Name:	Avanta Carpal Fusion Plating System
Device Classification:	Class II
Reviewing Panel:	Orthopaedic
Regulation Number	888.3030
Product Code:	HRS
Predicate Device:	KMI Wrist Fusion System (K991873) Acumed Wrist Fusion Plate (K021321)

Device Description:

The Avanta carpal fusion plate is a low profile single piece construct designed to fit over the dorsal aspect of the carpal bones in the hand. The plate has spherical holes or slots that accommodate screws for fixation. The plate and screws are fabricated from implantable grade stainless steel. Appendix 3 contains engineering drawings.

Intended Use:

The Avanta carpal fusion plate is designed for fusion of the carpal bones of the hand including; capitate, hamate, lunate, and triquetrum. The fusion plate is intended for use in patients suffering from pain and/or loss of function due to osteoarthritis, post-traumatic

arthritis, fractures, revision of failed partial wrist fusions, carpal instability, or rheumatoid arthritis. The fusion plate is used in conjunction with screws that fix the plate to the carpal bones of the hand.

Comparison to Predicate Device: (Appendix 4 contains predicate device literature.)

The table below summarizes similarities and differences between the Avanta, KMI, and Acumed plates.

Item	Avanta	KMI	Acumed
Product Name	Carpal Fusion Plate	KMI Wrist Fusion System	Acumed Wrist Fusion Plate
Use	Single use	Single use	Single use
Fixation	Bone screw	Bone screw	Bone screw
Material	Stainless steel	Stainless steel	Titanium
Indications for use	Intended for use in patients suffering from pain and/or loss of function due to osteoarthritis, post-traumatic arthritis, fractures, revision of failed partial wrist fusions, carpal instability, or rheumatoid arthritis.	Same indications	Same indications

Summary:

The Avanta device and the predicate devices studied have similar design characteristics and intended use. The safety and effectiveness of the Avanta Carpal Fusion Plate is substantially equivalent to the predicate devices mentioned above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 0 2003

Mr. H. Doug Plunkett
Director
Avanta Orthopaedics, Inc.
8600 Evergreen Boulevard
Minneapolis, Minnesota 55433

Re: K030881
Trade Name: Avanta Carpal Fusion Plating System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliance and Accessories
Regulatory Class: II
Product Code: HRS
Dated: March 19, 2003
Received: March 20, 2003

Dear Mr. Plunkett:

We have reviewed your Section 510(k) premarket 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) 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 Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Milkerson

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): K030881
Device Name: Carpal Fusion Plating System

Indications for Use:

The Avanta carpal fusion plate is designed for fusion of the carpal bones of the hand including; capitate, hamate, lunate, and triquetrum. The fusion plate is intended for use in patients suffering from pain and/or loss of function due to osteoarthritis, post-traumatic arthritis, fractures, revision of failed partial wrist fusions, carpal instability, or rheumatoid arthritis. The fusion plate is used in conjunction with screws that fix the plate to the carpal bones of the hand.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over the Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

for Mark N Milhous

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

510(k) Number K030881