DEC 4 1998

K982268

AVANTA
ORTHOPAEDICS

510 (k) Summary

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

Prepared: June 26, 1998

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:	Wrist joint ulnar (hemi-wrist) prosthesis
Device Trade Name:	Ulnar head implant
Device Classification:	Class II
Reviewing Panel:	Orthopedic
Regulation Number	888.3810
Product Code:	87 KXE
Predicate Device:	Silastic Swanson Ulnar Head Implant originally by Dow Corning Corporation, then Dow Corning Wright and Wright Medical which has been marketed since 1971.
Registration Number:	2030506
Owner Operator Number:	9001389

Device Description:

The ulnar head implant like the predicate device includes various sizes of implants and accessories including sizers. The implant allows for replacement of the distal ulnar head.

Indications for Use:

Avanta Orthopaedics Ulnar Head implant is intended for replacement of the distal radioulnar joint following ulnar head resection arthroplasty:

- Replacement of the distal ulnar head for rheumatoid, degenerative, or post-traumatic disabilities presenting the following:
    - Pain and weakness of the wrist joint not improved by conservative treatment

- Instability of the ulnar head with x-ray evidence of dorsal subluxation and erosive changes
- Failed ulnar head resection

Comparison to Predicate Device:

The legally marketed predicate device to which this device is substantially equivalent is the Dow Corning Corporation Silastic Swanson Ulnar Head Implant.

Regulatory Class: II
Product Code: 87 KXE

Item	*Avanta Product*	*Dow Corning/Wright Medical Technologies*
Product Name	Ulnar Head Implant	Silastic Swanson Ulnar Head Implant
Use	Single use	Single use
Fixation	stem in intramedullary canal	stem in intramedullary canal
Constraint	non constrained	non constrained
Material	Co-Cr.	Silicone
Sizes	3 sizes, 1, 2, 3	7 sizes 1-7
Indications for use	Avanta Orthopaedics Ulnar Head implant is intended for replacement of the distal radioulnar joint following ulnar head resection arthroplasty: Replacement of the distal ulnar head for rheumatoid, degenerative, or post-traumatic disabilities presenting the following: pain and weakness of the wrist joint not improved by conservative treatment instability of the ulnar head with x-ray evidence of dorsal subluxation and erosive changes failed ulnar head resection	Silastic Swanson Ulnar Head implant is intended for replacement of the distal radioulnar joint following ulnar head resection arthroplasty: Replacement of the distal ulnar head for rheumatoid, degenerative, or post-traumatic disabilities presenting the following: pain and weakness of the wrist joint not improved by conservative treatment instability of the ulnar head with x-ray evidence of dorsal subluxation and erosive changes failed ulnar head resection

Similarities of the Avanta Orthopaedics Radial Head Implant and the Dow Corning/Wright Medical Technology, Inc. Ulnar Head Implant include;
Both devices are intended for single use only; Both devices are intended for surgical implantation longer than 30 days; Both devices are placed into the intramedullary canal of the distal end of the ulna; Both devices are made of industry standard materials. No new materials are introduced in either product; Both devices are comparably sized; Both devices have the same indications for use.

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

DEC 4 1998

Ms. Louise M. Focht
Avanta Orthopedics
9369A Carroll Park Drive
San Diego, California 92121

Re: K982268
Trade Name: Ulnar Head Implant
Regulatory Class: II
Product Code: KXE
Dated: September 24, 1998
Received: September 25, 1998

Dear Ms. Focht:

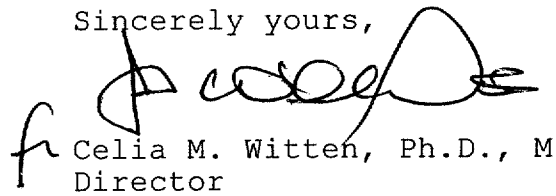
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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,



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

510 (k) Number (If Known): K982268
Device Name: Ulnar Head

Indications for Use:

Avanta Orthopaedics Ulnar Head implant is intended for replacement of the distal radioulnar joint following ulnar head resection arthroplasty:

- Replacement of the distal ulnar head for rheumatoid, degenerative, or post-traumatic disabilities presenting the following:
  - Pain and weakness of the wrist joint not improved by conservative treatment
  - Instability of the ulnar head with x-ray evidence of dorsal subluxation and erosive changes
  - Failed ulnar head resection

Prescription Use Yes OR Over the Counter Use No

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K982268