K023604 P1/2

NOV 27 2002

510 (k) Summary

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

Prepared: October 23, 2002

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

Telephone: 858-452-8580
Fax: 858-452-9945
Contact:

Device Name:	Radial Head Implant
Device Trade Name:	Radial head implant
Device Classification:	Class II
Reviewing Panel:	Orthopedic
Regulation Number	888.3170
Product Code:	87 KWI
Original Predicate Device:	Original 510k application Avanta Orthopaedics (K982288, K002644).
Registration Number:	2030506
Owner Operator Number:	9001389

Device Description:

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

Indications for Use:

Avanta Orthopaedics Radial Head implant is intended for replacement of the proximal end of the radius:

- Replacement of the radial head for degenerative, or post-traumatic disabilities presenting pain, crepitation and decreased motion at the radiohumeral and or proximal radio-ulnar joint with:
    - joint destruction or subluxation visible on x-ray
    - resistance to conservative treatment
- Primary replacement after fracture of the radial head
    - Symptomatic sequelae after radial head resection

Comparison to the Original Predicate Device:

The legally marketed predicate device to which this device is substantially equivalent is the Avanta Radial Head Implant.

Regulatory Class: II
Product Code: 87 KWI

Table 2. Comparison of the Avanta Radial Head Implants

Item	*Original Avanta Product*	*Proposed product configuration*
Product Name	Radial Head Implant	Radial Head Implant
Use	Single use	Single use
Fixation	stem in intramedulary canal	stem in intramedulary canal
Constraint	non constrained	non constrained
Material	Co-Cr/CpTi	Co-Cr/CpTi/UHMWPE
Sizes	4 sizes, 2, 3,4N,4	4 sizes, 2, 3,4N,4
Indications for use	Avanta Orthopaedics Radial Head implant is intended for replacement of the proximal end of the radius: Replacement of the radial head for degenerative, or post-traumatic disabilities presenting pain, crepitation and decreased motion at the radio-humeral and/or proximal radio-ulnar joint with : • joint destruction or subluxation visible on x-ray • resistance to conservative treatment Primary replacement after fracture of the radial head Symptomatic sequelae after radial head resection	Avanta Orthopaedics Radial Head implant is intended for replacement of the proximal end of the radius: Replacement of the radial head for degenerative, or post-traumatic disabilities presenting pain, crepitation and decreased motion at the radio-humeral and/or proximal radio-ulnar joint with : • joint destruction or subluxation visible on x-ray • resistance to conservative treatment Primary replacement after fracture of the radial head Symptomatic sequelae after radial head resection

Similarities of the Avanta Orthopaedics Radial Head Implant and the Avanta Predicate Radial 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 proximal end of the radius; 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.

Mechanical testing has been performed to demonstrate substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 27 2002

Mr. Doug Plunkett
Avanta Orthopedics, Inc.
9639 Carroll Park Drive, Suite A
San Diego, California 92121

Re: K023604
Trade/Device Name: Radial Head Implant
Regulation Number: 21 CFR §888.3170
Regulation Name: Elbow joint radial (hemi-elbow) polymer prosthesis
Regulatory Class: Class II
Product Code: KWI
Dated: October 23, 2002
Received: October 28, 2002

Dear Mr. Plunkett;

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 Melkerson

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

510 (k) Number (If Known): K023604
Device Name: Radial Head

Indications for Use:

Avanta Orthopaedics Radial Head implant is intended for replacement of the proximal end of the radius:

- Replacement of the radial head for degenerative, or post-traumatic disabilities presenting pain, crepitation and decreased motion at the radiohumeral and or proximal radio-ulnar joint with:
  - joint destruction or subluxation visible on x-ray
  - resistance to conservative treatment
- Primary replacement after fracture of the radial head
  - Symptomatic sequelae after radial head resection

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K023604

Prescription Use _____ OR Over the Counter Use _____

(Per 21 CFR 801.109) (Optional Format 1-2-96)