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510(k) SUMMARY

SUBMITTER NAME: Ascension Orthopedics, Inc.
8700 Cameron Road, C–100
Austin, TX 78754-3832

510(k) CONTACT: Glen Neally
Phone: (512) 836-5001

TRADE NAME: Ascension® MUH

COMMON NAME: ulnar head prosthesis

CLASSIFICATION: 21 CFR §888.3810

PRODUCT CODE: 87 KXE

PANEL: Orthopedic

PREDICATE DEVICE:
Avanta Orthopaedics, Inc., Ulnar Head Implant (K010786)

DEVICE DESCRIPTION:
The Ascension® MUH implant is a single-use, two-component, modular prosthesis designed for replacement of the ulnar head. Components will be available in three head sizes, and nine stem sizes which are assembled by means of a taper connection. Device components are made from cobalt chromium alloy meeting ASTM F1537 and titanium Ti6Al4V ELI meeting ASTM F136, the same materials used to fabricate other ulnar head prostheses that have market clearance for sale in the United States.

INTENDED USE:
The Ascension® MUH implant is intended for replacement of the distal radioulnar joint:

Replacement of the distal ulnar head for rheumatoid, degenerative, or post-traumatic arthritis 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

BASIS OF SUBSTANTIAL EQUIVALENCE:
A comparison of identical materials and nearly identical design features, demonstrate that the Ascension® MUH is substantially equivalent to the predicate device as indicated in the chart below:

Comparison Feature	Ascension Modular Ulnar Head	Avanta Ulnar Head Implant
Design	Two-piece modular implant	Two-piece modular implant
Material (Head)	ASTM F1537 cobalt chromium	ASTM F1537 cobalt chromium
Material (Stem)	ASTM F136 Ti6Al4V ELI	CpTi
Assembly	Taper connection	Taper connection
Fixation	Stem in medullary canal	Stem in medullary canal
Articulation	Hemi	Hemi
Use	Single use only, surgical implantation longer than 30 days	Single use only, surgical implantation longer than 30 days
Sterilization by user	Resterilization of device is not recommended.	Resterilization of device is not recommended.
Packaging	Double barrier assembly in paperboard box	Double barrier assembly in paperboard box
Accessories	Sterilizable instrumentation is available separately (not provided sterile).	Sterilizable instrumentation is available separately (not provided sterile).
Stem surface finish	Roughened	Roughened
Available sizes	Three heads: (3 diameters) Nine stems	Three heads: (3 diameters) Six stems

Similarities of the Ascension® MUH implant and the Avanta Ulnar Head Implant include: Both devices have the same indications for use; Both devices are made of the same industry standard materials; No new materials are introduced in either product; Both devices are placed into the intramedullary canal of the distal end of the ulna; Both devices are a hemi articulation; Both devices are intended for surgical implantation longer than 30 days: Both devices are intended for single use only.

Summary:

The Ascension® MUH is functionally identical, comparably sized, and has a similar design as compared to the Avanta Ulnar Head Implant. Individual components for the subject and predicate device are provided sterile in individual packages. The Ascension® MUH shares identical indications for use with the predicate device, and is fabricated from the same material as the predicate device. Therefore, the Ascension® MUH 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

NOV - 3 2005

Glen Neally
Director of QA/RA
Ascension Orthopedics, Inc.
8700 Cameron Road, Suite 100
Austin, Texas 78754-3832

Re: K052137
Trade/Device Name: Ascension® MUH
Regulation Number: 21 CFR 888.3810
Regulation Name: Wrist joint ulnar (hemi-wrist) polymer prosthesis
Regulatory Class: II
Product Code: KXE
Dated: July 22, 2005
Received: August 5, 2005

Dear Mr. Neally:

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), please contact the Office of Compliance at (240) 276-0120. 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/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(K) Number: K052137

Device Name: Ascension® MUH

Indications for Use:

The Ascension® MUH is intended for replacement of the distal radioulnar joint:

Replacement of the distal ulnar head for rheumatoid, degenerative, or post-traumatic arthritis 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

Contraindications

- Malunited forearm fractures that preclude stabalization of the ulnar head during pronation/supination
- Tendon, ligament, or distal radioulnar joint which cannot provide adequate support or fixation for the prostheses
- Inadequate skin or musculotendinous system
- Growing patients with open epiphyses
- Previous open fracture or infection in or around the joint
  Known sensitivity to materials used in this device

Prescription Use X OR Over-The-Counter Use _____
(Part 21 CFR 801Subpart B) (Part 21 CFR 801Subpart C)

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Number K052137