OCT 5 - 2004

K 041858

ACUMED®,LLC

5885 N.W. Cornelius Pass Road, Hillsboro, Oregon 97124-9432 Tel (503) 627-9957

510(k) Summary

This summary regarding 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

Submitter Information: Acumed LLC
5885 N.W. Cornelius Pass Road
Hillsboro, OR 97124-9432
USA
Phone: (503) 627-9957
FAX: (503) 716-1001
Contact: Ed Boehmer, Regulatory & Documentation Supervisor

Classification Name:	Prosthesis, Elbow, Hemi-, Radial, Polymer
Common Name:	Elbow Hemi-, Prosthesis
Proprietary Name:	Acumed Anatomic Radial Head System
Proposed Regulatory Class:	Class II, 21 CFR 888.3170
Device Product Code:	KWI
Legally Marketed Equivalent Device(s):	Avanta Radial Head Implant K002644 Wright Medical Inc. Modular Radial Head K991915

Device Description: The Acumed Anatomic Radial Head System includes modular heads and stems with accessories to anatomically replace the proximal potion of the radius and restore the natural articulation of the radial head with the radial notch of the ulna and capitulum of the distal humerus.

Intended Use: The Acumed Anatomic Radial Head System is indicated for use in:

1. 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 and/or subluxation, resistance to conservative treatment.
2. Primary replacement after fracture of the radial head.
3. Symptomatic sequelae after radial head resection.
4. Revision following failed radial head arthroplasty

These are similar to intended use of predicate devices and do not raise new issues of safety and effectiveness.

Technological Characteristics: The Acumed Anatomic Radial Head System uses an elliptically shaped, highly polished cobalt alloy head (ASTM F1537) with a titanium alloy stem (ASTM F136). Both cobalt alloy and titanium alloy have been successfully used in numerous implant prostheses. There are no technological characteristics that raise new issues of safety or effectiveness.

An assessment of performance data is not applicable.
A discussion of clinical and non-clinical tests is not applicable.

Based upon the similarities of the Acumed Anatomic Radial Head System and the predicate devices studied, the safety and effectiveness of the Acumed Anatomic Radial Head System is substantially equivalent to the predicate devices referenced.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 5 - 2004

Mr. Ed Boehmer
Regulatory and Documentation Supervisor
Acumed, LLC
5885 N.W. Cornelius Pass Road
Hillsboro, Oregon 97124-9432

Re: K041858
Trade/Device Name: Acumed Anatomic Radial Head System
Regulation Number: 21 CFR 888.3170
Regulation Name: Elbow joint radial (hemi-elbow) polymer prosthesis
Regulatory Class: II
Product Code: KWI
Dated: July 8, 2004
Received: July 9, 2004

Dear Mr. Boehmer:

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.

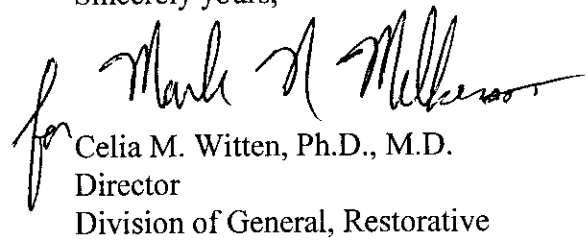
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (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,



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): K041858

Device Name: Acumed Anatomic Radial Head System

Indications For Use:

The Acumed Anatomic Radial Head System and accessories are designed specifically for:

1. 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 and/or subluxation, resistance to conservative treatment.
2. Primary replacement after fracture of the radial head.
3. Symptomatic sequelae after radial head resection.
4. Revision following failed radial head arthroplasty

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Millner

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

510(k) Number K041858