acumed®

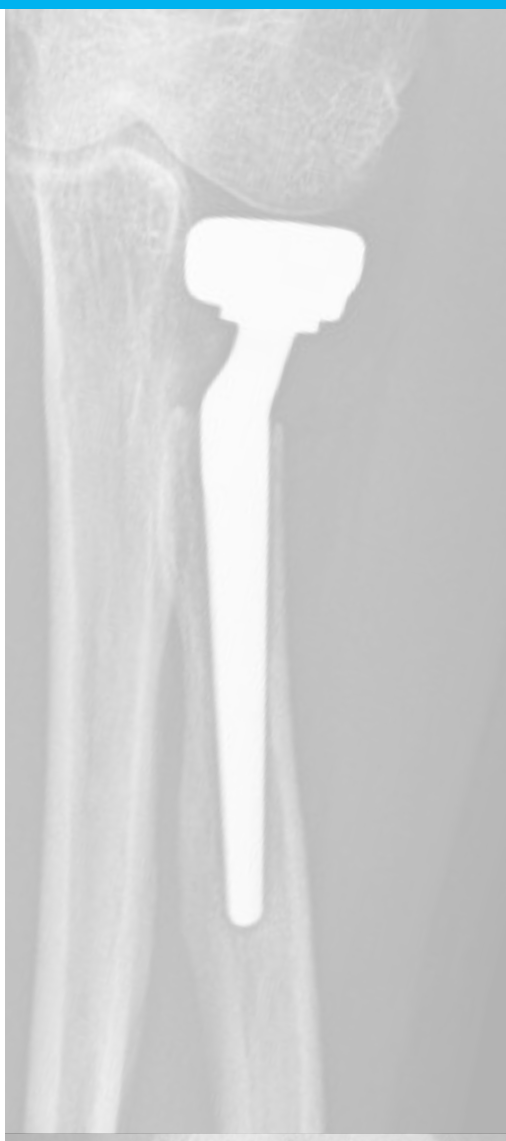
Anatomic Radial Head Solutions 2

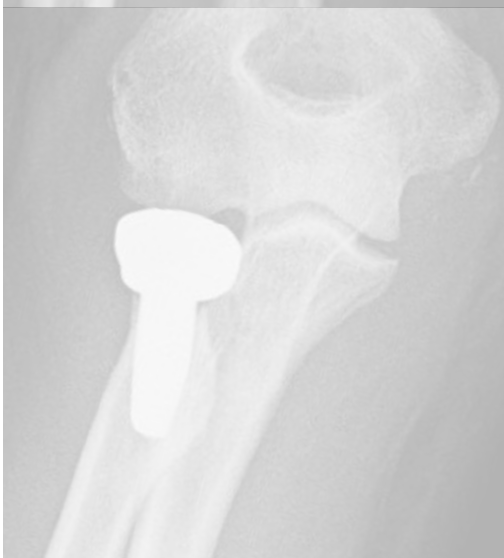
Value Analysis Committee Resource Guide

A COLSON ASSOCIATE

Acumed® is a global leader of innovative orthopaedic and medical solutions.

We are dedicated to developing products, service methods, and approaches that improve patient care.





Acumed Anatomic Radial Head Solutions 2

At Acumed, we support surgeons and health care providers who treat patients in their times of need. We are proud of our long-standing reputation of differentiation and our ability to consistently provide innovative solutions that benefit the whole health care community. We believe that together, we can improve patient outcomes and quality of life.

Designed in conjunction with Shawn W. O'Driscoll, PhD, MD, the Anatomic Radial Head Solutions 2 system includes 924 head and stem combinations and system-specific instrumentation designed to help streamline the surgeon's experience in the operating room.

Table of Contents

Solutions Overview

The Acumed Anatomic Radial Head Solutions 2 is designed to provide an anatomic implant to replace the patient's native radial head. The severity of radial head fractures can vary greatly in a case-by-case basis. Conservative, nonoperative treatment may not be suitable in some cases, and some radial heads cannot be salvaged with plates and/or screws. The best choice in these situations may be a radial head prosthesis.

The Acumed radial head prosthesis has an anatomically shaped radial head designed to mimic the radiocapitellar joint contact of a native radial head, which may reduce cartilage erosion and capitellum wear over time as compared to nonanatomic prostheses.[1,7] In addition to standard stems, long stems allow further options for revision surgery due to failed radial head arthroplasty, and for primary cases when the fracture extends distally into the radial neck.

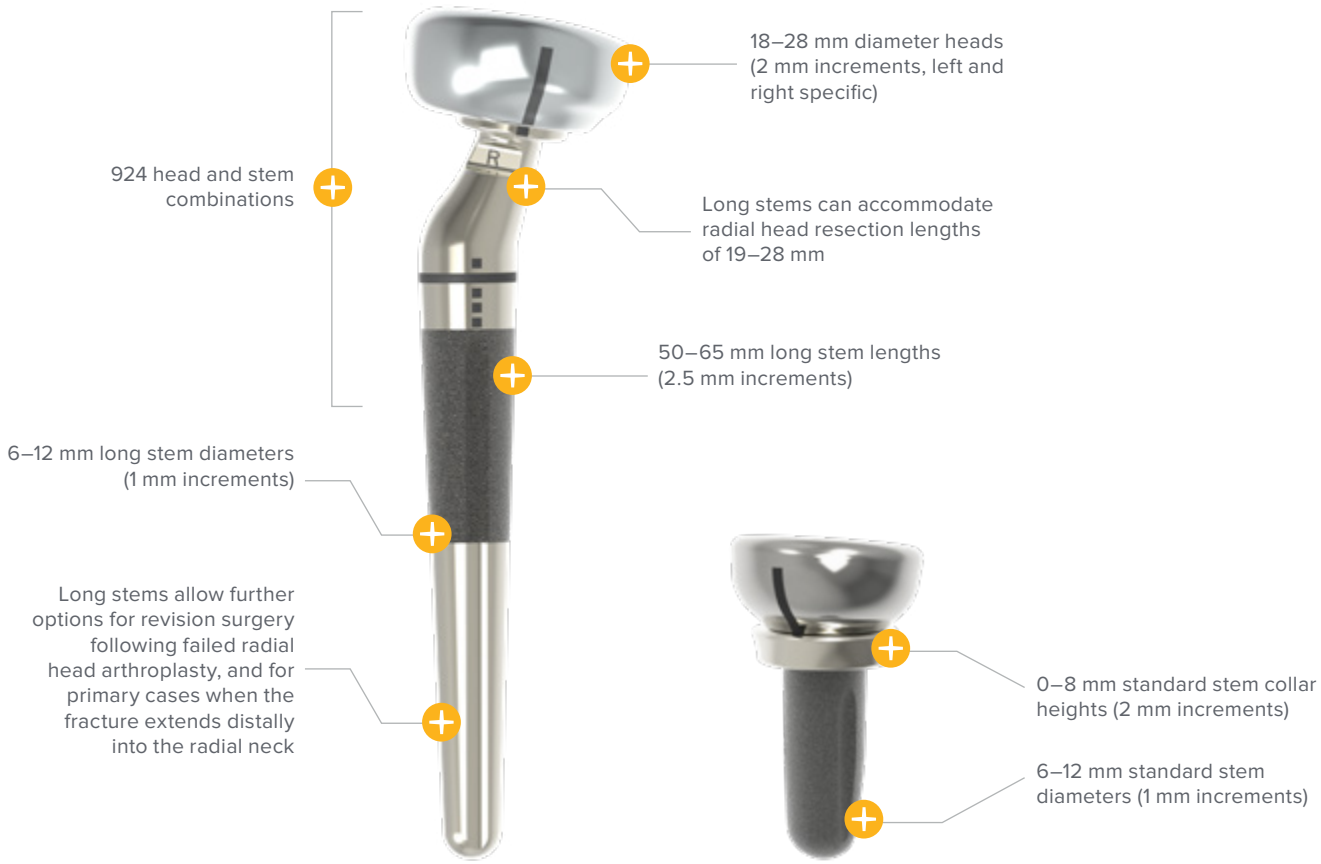
Designed in conjunction with Shawn W. O'Driscoll, PhD, MD, the system includes 924 head and stem combinations and system-specific instrumentation designed to help streamline the surgeon's experience in the operating room.

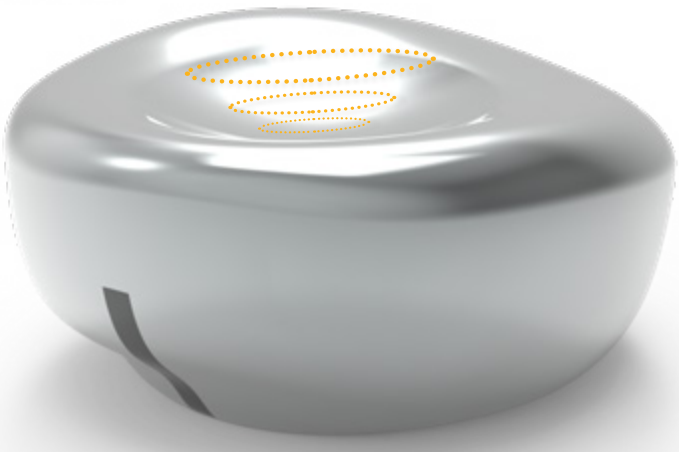
Indications for Use:

- Replacement of the radial head for degenerative or post-traumatic disabilities presenting pain, crepitation, and decreased motion at the radiohumeral and/or proximal radioulnar joint with:
  - joint destruction and/or subluxation
  - resistance to conservative treatment
- Primary replacement after fracture of the radial head
- Symptomatic sequelae after radial head resection
- Revision following failed radial head arthroplasty

In addition to the Anatomic Radial Head Solutions 2 system, this set may include the Acutrak 2® Mini and Micro instruments and the Locking Radial Head Plate System at the base of the tray to provide multiple solutions all in one set. For the Acutrak 2 Headless Compression Screw System surgical technique, please reference part number SPF00-02. For the Radial Head Plating System surgical technique, please reference part number ELB00-02.

Key System Features





Second Generation Head

- Compared to nonanatomic heads, the ARH Solutions 2 heads closely match native radial heads regarding contact with the lateral trochlear ridge and the capitellum. They are also less likely to yield contact pressures that can be harmful to cartilage.
- The dish depth increases with head diameter, which is designed to help improve radiocapitellar wear characteristics over nonanatomic heads and the first generation Acumed Anatomic Radial Head.[1,2]
- The head's medial surface is contoured to better replicate the lateral trochlear ridge facet, which may help avoid cartilage erosion.[2]

Instrumentation

- Reamers for radial canal preparation—reamers allow for a 1 mm larger stem diameter when compared to broaches, and may decrease risk of fracturing the radial neck.[3]
- Radius Retractor Tool—designed to help elevate the radius.

Facts About Radial Head Fractures

Fractures of the radial head account for 1.7–5.4% of all adult fractures, and are involved in 33% of elbow fractures.[4,5,6] Approximately 85% of radial head fractures occur in people who are young and active.[3] They are usually the result of a fall onto an outstretched hand when the elbow is partially flexed and pronated.[4]

Radial head and neck fractures are commonly diagnosed using the Mason classification,[4,5] which is as follows:

Mason Classification	Description
Type I	Nondisplaced radial head fracture[5]
Type II	Displaced radial head fracture with greater than 2–3 mm of step-off, greater than 30° of angulation, or greater than 30° of head involvement[5]
Type III	Comminuted radial head fracture[5]
Type IV	Radial head fracture with elbow dislocation[5]

Mason type I fractures are treated conservatively and Mason type II fractures can be treated by open reduction and internal fixation. However, the treatment methods of the Mason type III and type IV fractures can be controversial.[5] Options for these fractures may include open reduction and internal fixation, radial head excision, or radial head replacement.

Open reduction and internal fixation is only possible if the radial head is reconstructable. If there are other destabilizing injuries, radial head resection can result in elbow instability, posterolateral rotatory instability, and/or radial shortening relative to the ulna.[4,5,6,7] Radial head arthroplasty can be used with soft tissue repair to reduce the risk of elbow instability.[4,5,6] Since the prosthesis functions as a radial head, it must be able to withstand the loads and transmit the forces while providing lateral column stability.[5]

Facts About Radial Head Fractures [continued]

Publication Excerpts

"...reduced radiocapitellar contact areas and elevated contact pressures during compressive loading... were significantly greater with symmetrical circular prostheses than with asymmetrical elliptical designs. The prosthesis that best mimicked native contact behavior was the [ARH Solutions 2] owing to its design for articulating with the capitellum, the lateral trochlear ridge, and the sulcus between."[2]

"The geometry of radial head implants strongly influences their contact characteristics. In a direct radius-to-capitellum axial loading experiment, an anatomically designed radial head prosthesis had lower and more evenly distributed contact pressures than the nonanatomic implants that were tested."[1]

"Radial canal preparation with a reamer allowed for the accommodation of at least a 1 mm larger cementless, textured stem versus preparation with a rasp. Additionally, the initial stability of press-fit radial head implants is within the threshold conducive to bone ingrowth after reaming the canal, and is comparable to that achieved after rasping."[3]

"This study reviews the clinical experience with Anatomic Radial Head prosthesis, which is effectively restoring stability and congruency of the elbows with comminuted and irreparable radial head fracture and valgus laxity. There was no evidence of arthritic radiocapitellar joint, capitellar osteopenia, significant proximal radial migration of the implant, or any major complications. Patients recovered a similar range of motion between affected and unaffected elbows."[8]

"Prosthetic design features such as radius of curvature and maximum depth of articulating dish play a role in radiocapitellar stability. Implant designs may be important for patients in whom stability of the elbow is at risk."[9]

"The monopolar metallic head and the native radial head behaved similarly regarding resistance to subluxation. The bipolar head behaved in an entirely opposite manner than the native and monopolar head and actually acted to facilitate subluxation."[10]

Competitive Comparison

Feature	Acumed Anatomic Radial Head Solutions 2	Wright Medical Evolve Proline Radial Head System
Material	Cobalt chrome	Cobalt chrome
Head Diameters	18 mm, 20 mm, 22 mm, 24 mm, 26 mm, 28 mm left and right specific	18 mm, 20 mm, 22 mm 24 mm, 26 mm, 28 mm
Stem Material	Partially or fully grit-blasted titanium	Polished titanium alloy
Long Stem Diameters	6–12 mm (1 mm increments)	N/A
Long Stem Lengths	50 mm, 52.5 mm, 55 mm, 57.5 mm, 60 mm, 62.5 mm, 65 mm	N/A
Min/Max Resection Lengths	9–17 mm (standard stem) 19–28 mm (long stem)	8.5–19 mm
Head/Collar Heights	**Head height:** 8 mm net height when measured from the bottom of the head to the bottom of the dish **Neck heights**: +0 mm, +2 mm +4 mm, +6 mm, +8 mm (standard stems only)	**Head height:** 8.5–15 mm **Neck Heights:** +0 mm, +2 mm, +4 mm
Connection Point	Morse taper	Morse taper
Standard Stem Diameters	6 mm, 7 mm, 8 mm 9 mm, 10 mm, 11 mm, 12 mm	4.5 mm, 5.5 mm, 6.5 mm 7.5 mm, 8.5 mm, 9.5 mm
Standard Stem Lengths	25 mm	20–25 mm (grows with diameter)
Canal Preparation	Reamers	Broaches

Competitive Comparison [continued]

Skeletal Dynamics ALIGN Radial Head System	Tornier Radial Head System	Zimmer Biomet L2L Radial Head System	Zimmer Biomet ExploR Modular Radial Head System
Cobalt chrome	Cobalt chrome	Cobalt Chrome	Cobalt chrome
18 mm, 20 mm, 22 mm 24 mm, 26 mm	18 mm, 20 mm, 22 mm, 24 mm	18 mm, 20 mm, 22 mm, 24 mm, 26 mm, 28 mm	20 mm, 22 mm, 24 mm
Partially grit-blasted stem (Ti)	Short stem – CoCr (stem shaft Ti plasma spray), Long stem – smooth CoCr	Polished titanium alloy	Partially grit-blasted titanium alloy
	6.5 mm or 8 mm	N/A	N/A
N/A	55 mm or 60 mm	N/A	N/A
15–23 mm	13 or 16 mm (Short Stems) 19 or 22 mm (Long Stems)	9–18 mm	12 mm (min)
Heights: 15 mm, 17 mm 19 mm, 21 mm, 23 mm	**Short stem neck heights:** 13 mm, 16 mm **Long stem neck heights:** 19 mm or 22 mm	**Head heights** increase by +1 mm by diameter **Neck heights:** +0, +2, +4 mm	**Head heights:** 10 mm, 12 mm 14 mm, 16 mm, 18 mm
Side-loading with set screw	Bipolar snap-fit	Morse taper	Side-loading with set screw
7 mm, 8 mm, 9 mm 10 mm, 11 mm	6 mm, 7 mm, 8 mm 9 mm, 10 mm	5 mm, 6 mm, 7 mm, 8 mm, 9 mm, 10 mm	5 mm, 6 mm, 7 mm 8 mm, 9 mm
29 mm, 30 mm, 33 mm 35 mm, 37 mm	21 mm, 22 mm, 23 mm, 24 mm	N/A–length increases by diameter	22 mm, 24 mm, 26 mm 28 mm, 30 mm
Broaches	Short stem reamer long stem reamer	Offset reamer	Curved broaches

501(k) Clearance Information

Acumed Anatomic Radial Head Long Stems and ARH Slide-Loc™ System
510(k) Notification

K131845

510(k) Summary

Contact Details

Applicant Name: Acumed LLC
5885 NW Cornelius Pass Road, Hillsboro, OR 97124-9432

Kara Budor, Regulatory Specialist
503-207-1412

Date Prepared: June 19, 2013

SEP 3 0 2013

Device Name

Trade Name: Acumed Anatomic Radial Head System
Acumed Anatomic Radial Head Long Stems
Acumed ARH Slide-Loc™ System

Common Name: Elbow Hemi-, Prosthesis

Classification: 21 CFR 888.3170 Elbow joint radial (hemi-elbow) polymer prosthesis

Class: II

Product Code: KWI

Legally Marketed Predicate Device(s)

The Anatomic Radial Head System cleared in 2004 (K041858) serves as the predicate device.

Device Description

The Acumed Anatomic Radial Head Long Stems and the Acumed ARH Slide-Loc™ System include modular heads and stems with accessories to anatomically replace the proximal portion 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/Indications for use

The Acumed Anatomic Radial Head System, the Anatomic Radial Head Long Stems, the ARH Slide-Loc™ System, and accessories are designed specifically for:

501(k) Clearance Information [continued]

K131845

Acumed Anatomic Radial Head Long Stems and ARH Slide-Loc™ System
510(k) Notification

1. 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 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.

The device is intended to be press fit or cemented.

Substantial Equivalence Comparison

The basic comparison between the Anatomic Radial Head Long Stems and the ARH Slide-Loc™ System to the Acumed Anatomic Radial Head System is given in the table below.

	Anatomic Radial Head Long Stems and the ARH Slide-Loc™ System	Predicate
Material	Titanium alloy per ASTM F136 Cobalt Chromium per ASTM 1537	Titanium alloy per ASTM F136 Cobalt Chromium per ASTM 1537
Head Diameter	18mm to 30mm	20mm to 28mm
Stem Diameter	5mm to 12mm	6mm to 10mm
Stem Length	25mm to 65mm	22mm
Stem Finish	Grit Blast	Grit Blast
Head-to-Stem Connection	Slide-Loc™ groove and rail connection with neck component and/or Morse Taper	Morse Taper
Head Configuration	Neutral or Left/Right Specific	Neutral
Stem Configuration	Neutral or Left/Right Specific	Neutral
Provided Sterile / Non-sterile	Sterile	Sterile

The Anatomic Radial Head Long Stems, the ARH Slide-Loc™ System, and the Anatomic Radial Head System all include implants and instruments used to replace the radial head. There are some differences, but none of them raise new issues of safety or effectiveness. The Anatomic Radial Head Long Stems and the ARH Slide-Loc™ System are substantially equivalent to the Acumed Anatomic Radial Head System.

Non-clinical Testing

The Anatomic Radial Head Long Stems and the ARH Slide-Loc™ System underwent static and cyclic load testing to characterize their strength.

501(k) Clearance Information [continued]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Acumed, LLC
Ms. Kara Budor
Regulatory Specialist
5885 North West Cornelius Pass Road
Hillsboro, Oregon 97124

September 30, 2013

Re: K131845
Trade/Device Name: Acumed Anatomic Radial Head System
Acumed Anatomic Radial Head Long Stems
Acumed ARH Slide-Loc™ System
Regulation Number: 21 CFR 888.3170
Regulation Name: Elbow joint radial (hemi-elbow) polymer prosthesis
Regulatory Class: Class II
Product Code: KWI
Dated: August 30, 2013
Received: September 3, 2013

Dear Ms. Budor:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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

501(k) Clearance Information [continued]

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Elizabeth L. Frank -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

501(k) Clearance Information [continued]

Acumed Anatomic Radial Head Long Stems and ARH Slide-Loc™ System
510(k) Notification

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Indications for Use

510(k) Number (if known): K131845

Device Name: Acumed Anatomic Radial Head System
Acumed Anatomic Radial Head Long Stems
Acumed ARH Slide-Loc™ System

Indications for Use:

The Acumed Anatomic Radial Head System, the Acumed Anatomic Radial Head Long Stems, the Acumed ARH Slide-Loc™ 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 radiohumeral 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.

The device is intended to be press fit or cemented.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.
Division of Orthopedic Devices

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501(k) Clearance Information [continued]

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.

501(k) Clearance Information [continued]

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.

501(k) Clearance Information [continued]

Page 2 – Mr. Ed Boehmer

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 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

501(k) Clearance Information [continued]

Page 1 of 1

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 Millerson

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

510(k) Number K041858

Our mission is to aid the afflicted through the ingenuity of our minds, the labor of our hands, and the compassion of our hearts.

Dedicated to Excellence

From manufacturing to business practices to product innovation, Acumed has an unwavering commitment to excellence. It is reflected in the honors received from industry peers and in the performance of our suite of surgical fixation solutions.

The AME Manufacturing Excellence Award

In 2011, Acumed received the AME Manufacturing Excellence Award, an honor recognizing North American manufacturing sites that have demonstrated operational excellence through continuous improvement, best practices, creativity, and innovation. This award supports AME's vision, mission and values of inspiring commitment to enterprise excellence through shared learning and access to best practices.

The Association for Manufacturing Excellence is North America's premier organization for the exchange of knowledge in Organizational Excellence through the implementation of techniques such as Lean Tools, Leadership, Lean Product Development, Lean Supply Chain, and Lean Accounting.

The Frost & Sullivan Manufacturing Leadership 100 Operational Excellence Award

In 2013, Acumed received the Frost & Sullivan Manufacturing Leadership 100 award for Operational Excellence, an honor recognizing the top 100 global manufacturing companies who are shaping the future through projects that deliver outstanding value, innovation, and return on investment.

Frost & Sullivan Manufacturing Leadership 100 is the world's first member-driven leadership network with knowledge in manufacturing leadership. It was created through a global community of executives working within the manufacturing industry.

A Leader in Product Development and Innovation

Acumed began developing products for elbow fixation in 1999 and released the first anatomically shaped radial head prosthesis in 2004. Since then, Acumed has grown to become one of the technology leaders in anatomic options for operative treatment of the elbow.[1] Acumed will continue to devote resources to the development of implants that aid in improving patient outcomes and advance the field of orthopaedic surgery.

1. iData Research Inc. 2012. U.S. Market for Small Bone & Joint Orthopedic Devices. Retrieved March 26, 2013 from www.idataresearch.net

Dedicated to Excellence [continued]

Industry Compliance

As a logo member of the Advanced Medical Technology Association (AdvaMed), Acumed endorses the AdvaMed Code of Ethics. Adherence to this Code ensures ethical interaction with healthcare professionals. Acumed requires anti-corruption training for employees interacting with healthcare professionals or government officials (foreign or domestic). In addition, Acumed sales representatives in the United States as well as international distribution partners must complete anti-corruption training programs.

Acumed also supports the United Nations Global Compact and Boston College Center for Corporate Citizenship organizations.

Transparency in Business Practice

Acumed tracks and reports spending in accordance with the Physician Payment Sunshine Act. In order to become an Acumed partner, all distributors must go through a due diligence analysis and a robust training and education program to ensure they share Acumed's values with respect to anti-corruption and compliance. Acumed maintains ethical behaviors with respect to compliance standards and laws.

A Commitment to Social Responsibility

At Acumed we understand that being an outstanding orthopaedics company is about more than creating top quality products: it's about being aware of the contributions we as an organization make to the world around us. Our company culture puts a great amount of emphasis on responsible business practices, the mindful stewardship of resources, and support for local and global humanitarian efforts.

The Charitable Giving Committee supports Acumed's commitment to helping those in need through educational initiatives, community action, and volunteerism. Beneficiaries include the Oregon Food Bank, STEM (Science, Technology, Engineering, Math) Connect, and SIGN Fracture Care International.

The Green Team educates and engages employees in sustainable practices that make a difference both at Acumed and at home. Eco-friendly landscaping, recycling events, weather-smart irrigation controls, and dedicated efforts to reduce power consumption are just a few of our green initiatives. In 2015, Acumed received special recognition for Excellence in Employee Engagement from the Energy Trust of Oregon. This recognition was the result of the work of the Acumed Green Team and the strategies they developed and enacted in order to bring more awareness to issues related to energy savings and environmental stewardship.

References

Citations

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