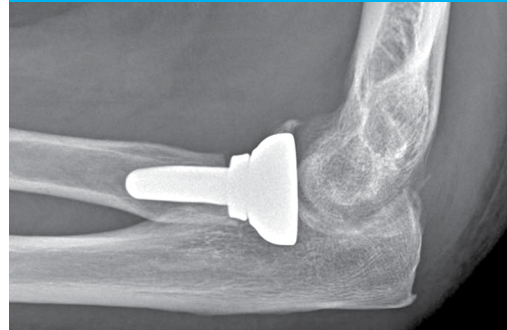


Value Analysis  
Committee  
Resource Guide



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.



## About Acumed®

At Acumed, we're constantly seeking to advance the field of orthopaedics. We design every product to best serve the patient, surgeon, hospital, and the collective outcome. And with everyone working together, these solutions have the power to support more than just the individual. They can transform the whole healthcare community.

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



## Anatomic Radial Head Solutions Overview



The Acumed Anatomic Radial Head System 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, non-operative treatment may not be suitable in some cases; furthermore, 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 non-anatomic prostheses.<sup>17</sup> 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, Ph.D., M.D., the system includes 290 head and stem combinations including standard stems, long stems, an anatomically shaped radial head, 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 radio-humeral and/or proximal radio-ulnar 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 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 Locking Radial Head Plate System surgical technique, please reference part number ELB00-02.

### ACUMED ANATOMIC RADIAL HEAD SYSTEM KEY FEATURES

- 290 head and stem combinations
- System can accommodate radial head resection lengths of 9–28 mm
- 20–28 mm diameter heads (2 mm increments, left and right specific)
- 6–10 mm standard stem diameters (1 mm increments)
- 0–8 mm standard stem collar heights (2 mm increments)
- 6–12 mm long stem diameters (2 mm increments, left and right specific)
- 50–65 mm long stem lengths (5 mm increments, left and right specific)
- 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.
- Anatomically shaped radial head prosthesis—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 non-anatomic prostheses.<sup>17</sup>
- 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.<sup>2</sup>
- Radius Retractor Tool—designed to help elevate the radius.

## Facts on 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.<sup>3,4,5</sup>

Approximately 85% of radial head fractures occur in people who are young and active.<sup>3</sup> They are usually the result of a fall onto an outstretched hand when the elbow is partially flexed and pronated.<sup>3</sup>

Radial head and neck fractures are commonly diagnosed using the Mason classification,<sup>3,4</sup> which is as follows:

- Type I: Nondisplaced radial head fracture<sup>4</sup>
- 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<sup>4</sup>
- Type III: Comminuted radial head fracture<sup>4</sup>
- Type IV: Radial head fracture with elbow dislocation<sup>4</sup>

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.<sup>4</sup> 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.<sup>3,4,5,6</sup> Radial head arthroplasty can be used with soft tissue repair to reduce the risk of elbow instability.<sup>3,4,5</sup> 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.<sup>4</sup>



### PUBLICATION EXCERPTS

*“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 non-anatomic implants that were tested.”<sup>1</sup>*

*“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.”<sup>2</sup>*

*“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.”<sup>7</sup>*

*“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.”<sup>8</sup>*

*“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.”<sup>9</sup>*

## Competition

	Acumed® Anatomic Radial Head Solutions	Synthes® Radial Head Prosthesis System	Tornier® RHS™ Radial Head System
<b>Head Material</b>	Cobalt Chrome	Cobalt Chrome	Cobalt Chrome
<b>Head Diameters</b>	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	18 mm, 20 mm, 22 mm, 24 mm
<b>Head/Collar Heights</b>	Collar Heights: +0 mm, +2 mm, +4 mm, +6 mm, +8 mm	Head Heights: +0 mm, +2 mm, +4 mm, +6 mm	Short Stem Neck Heights: 13 mm or 16 mm  Long Stem Neck Heights: 19 mm or 22 mm
<b>Connection Point</b>	Morse Taper	Side-loading with set screw	Bipolar Snap-fit
<b>Stem Material</b>	Grit-blasted Titanium Alloy	Chemical-etched Titanium	Ti Plasma-sprayed Cobalt Chrome (Short Stem)  Smooth CoCr (Long Stem)
<b>Standard Stem Diameters</b>	6 mm, 7 mm, 8 mm, 9 mm, 10 mm	6 mm, 7 mm, 8 mm, 9 mm, 10 mm	6 mm, 7 mm, 8 mm, 9 mm, 10 mm
<b>Standard Stem Lengths</b>	25 mm	24 mm, 26 mm, 28 mm, 30 mm, 32 mm	21 mm, 22 mm, 23 mm, 24 mm
<b>Long Stem Diameters</b>	6 mm, 8 mm, 10 mm, 12 mm	6 mm, 7 mm, 8 mm, 9 mm, 10 mm	6.5 mm or 8.5 mm
<b>Long Stem Lengths</b>	50 mm, 55 mm, 60 mm, 65 mm	40 mm, 42 mm, 44 mm, 46 mm, 48 mm	55 mm or 60 mm
<b>Min/Max Resection Lengths</b>	9 mm–28 mm	12.5 mm–21 mm	13 mm–22 mm
<b>Canal Preparation</b>	Reamers	Broaches	Short Stem Broaches  Long Stem Reamers

	<b>Biomet® EXPLOR® Modular Radial Head</b>	<b>Small Bone Innovations® rHead™ and rHead Extended Stem</b>
<b>Head Material</b>	Cobalt Chrome	Cobalt Chrome
<b>Head Diameters</b>	20 mm, 22 mm, 24 mm	18 mm, 21 mm, 24 mm
<b>Head/Collar Heights</b>	Head Heights: 10 mm, 12 mm, 14 mm, 16 mm, 18 mm	Standard Stem Collar Heights: +2 mm, +6 mm (varying head heights)  Long Stem Head Heights: 9 mm, 12 mm, 15 mm
<b>Connection Point</b>	Side-loading with set screw	Morse Taper
<b>Stem Material</b>	Bond-coated Titanium Alloy	Cobalt Chrome with Plasma-sprayed Titanium
<b>Standard Stem Diameters</b>	5 mm, 6 mm, 7 mm, 8 mm, 9 mm	6.4 mm, 7.2 mm, 8 mm, 8.8 mm
<b>Standard Stem Lengths</b>	22 mm, 24 mm, 26 mm, 28 mm, 30 mm	16 mm, 18 mm, 20 mm, 22 mm
<b>Long Stem Diameters</b>	N/A	4.5 mm, 5.5 mm, 6.5 mm, 7.5 mm
<b>Long Stem Lengths</b>	N/A	50 mm
<b>Min/Max Resection Lengths</b>	12 mm (min)	N/A
<b>Canal Preparation</b>	Rasps	N/A

## 510(k) Information

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

K131845

### 510(k) Summary

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#### 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

#### 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

SEP 30 2013

#### 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:



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.

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



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: KW1

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

Page 2 – Ms. Kara Budor

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

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

Page 1/1

### 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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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



OC1 5 - 2004

K 041858

ACUMED<sup>®</sup>, 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 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: 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

OCT 5 - 2004

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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: K.WI  
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.

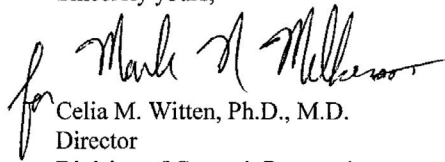
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

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,

A handwritten signature in black ink, appearing to read "for Celia M. Witten". The signature is written in a cursive style and is positioned to the left of the typed name.

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

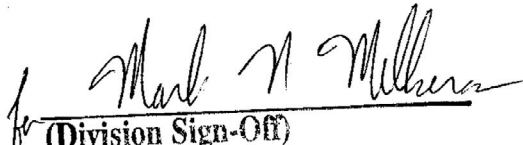
Prescription Use    
 (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_   
 (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 (Division Sign-Off)  
Division of General, Restorative,  
and Neurological Devices

510(k) Number K041858



## 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.<sup>1</sup> 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](http://www.idataresearch.net)



## 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

In 2012, the company began preparing to track and report 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.



## GREEN INITIATIVES

Acumed has formed a cross-functional group dedicated to preserving the environment and educating Acumed employees on the benefits of being "green." The Green Team's purpose statement is:

*We empower Acumed and the global community through education, encouragement, and execution of sustainable business practices. By doing this, we engage our sphere of influence to deliver innovative products that respect the community's natural systems, support ethical equity, and drive customer loyalty.*

The Acumed vision includes being respectful stewards of our local community and global environment, and a large part of this is our commitment to "green" initiatives.

### No Bottled Water Pledge

The Green Team sponsored a "no bottled water" pledge program to reduce the consumption of bottled water by Acumed. To date, over 200 employees have pledged to avoid drinking bottled water while on site or traveling domestically on behalf of Acumed. In addition, during on site sales rep trainings, attendees are provided with reusable water bottles.

### Papercut

Acumed is committed to reducing paper consumption in our daily business operations. The Green Team drove projects to reduce paper consumption and will expand this to reduce overall landfill waste. Activities include eliminating paper stubs, defaulting to double-sided printing and copying, and providing compostable lunchroom supplies.

## REFERENCES

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© 2014 Acumed® LLC

Acumed® Headquarters  
5885 NW Cornelius Pass Road  
Hillsboro, OR 97124

Office: 888.627.9957  
Fax: 503.520.9618  
acumed.net

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