JAN - 7 2014

4. 510(k) Summary

K132735

Innovative Medical Device Solutions

Applicant/Sponsor: **IMDS (Innovative Medical Device Solutions)**
Corporate Headquarters
13600 Heritage Parkway, Suite 170
Fort Worth, TX 76177

Contact Person: **Andrew Rynearson**
Regulatory Council
IMDS (Innovative Medical Device Solutions)
2710 Discovery Dr, Ste 600
Orlando, FL 32826
arynearson@imd.net
Phone: (407) 770 0258
Fax: (407) 770 0231

Date: **1/6/14**

DEVICE INFORMATION

Proposed Trade Name: **Axia Radial Head System**

Common Name: **Elbow Hemi-, Prosthesis**

Classification Name: **Elbow joint radial (hemi-elbow) polymer prosthesis per 21 CFR 888.3170. This falls under the Orthopedics panel/87 as a Class II device.**

Device Product Code: **KWI**

Predicate Devices: **Evolve® Radial Head System (K060731)**

Device Description:

The Axia Radial Head System is a 2-part system comprised of a radial head implant and a radial stem implant. There are 6 sizes of radial heads and 6 sizes of stems. Each stem implant is available in 3 offset sizes. The large combination of implant sizes and the amount size interchangeability in the system allows for better reproduction of individual patient anatomy.

The Axia Radial Head System radial head implants are made from cobalt-chromium-molybdenum (Co-Cr-Mo) alloy. The radial head stems are made from titanium alloy (Ti-6Al-4V).

Intended Use:

Radial head arthroplasty

Indications for Use:

The Axia Radial Head System is intended to reduce or relieve pain and restore function and motion to the elbow.

- Radial head replacement for degenerative or post-traumatic disabilities when presenting with 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 radial head replacement after fracture
- Symptomatic sequelae after radial head resection
- Revision following failed radial head arthroplasty

CAUTION: This device is intended for uncemented use only.

Summary of Technological Characteristics

Table 1: Feature Comparison of Subject and Predicate Heads

	Heads	
	Axia Heads (Subject)	**Wright Evolve Radial Head (Predicate)**
Material	CoCrMo (ASTM F1537)	CoCrMo (ASTM F1537)
Sizes	6 Sizes	6 Sizes
Diameters size range	18mm - 28mm	18mm – 28mm
Height size range	1 height per size	+2mm offset +4mm offset
Connection to stem	Taper connection	Taper connection
Surface finish	Polished articular surface	Polished articular surface

Table 2: Feature Comparison of Subject and Predicate Stems

	Stems	
	Axia Stems (Subject)	**Wright Evolve Stems (Predicate)**
Material	Ti6Al4V (ASTM F136)	CoCrMo (ASTM F1537)
Sizes	6 Sizes	6 Sizes
Diameter Options	5mm - 10mm	4.5mm – 9.5mm
Offset Options	+0mm +2mm +4mm	+0mm +2mm +4mm
Connection to head	Taper connection	Taper connection
Surface finish	Polished	Polished
Fixation	Non cemented	Non cemented

The Axia and Evolve radial head systems share the following indications:

- Radial head replacement is indicated for degenerative or post-traumatic disabilities when presenting with 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 radial head replacement after fracture
- Symptomatic sequelae after radial head resection
- Revision following failed radial head arthroplasty.

The Axia and Evolve radial head systems share the following technological characteristics:

- Co28CrMo (ASTM 1537) head Implants
- 6 sizes of head implants ranging from 18mm-28mm
- Taper Connection to stem
- Polished articular surfaces on head implant
- 6 sizes of stem implants
- +0, +2, +4, offset options
- Polished stem surface
- Non cemented use
- Axially symmetric geometry

The technological features of the Axia Radial Head System are substantially equivalent to the predicate device.

Performance Testing

The following tests were performed in this submission:

1. Modular Connection Testing per ASTM F 2009.

An evaluation of the taper connection was performed to determine the resistance to component disassembly. The testing was performed in accordance with ASTM F2009 (Standard Test Method for Determining Axial Disassembly Force of Taper Connections of Modular Prostheses) using worst case test components and worst case assembly conditions. The results were compared with loads reported in the clinical literature for high demand patient activities. This comparison showed that the worst case taper connection strength is equivalent to 9 times the peak in vivo force when assembled using the worst case assembly method. When using the assembly method in the recommended surgical technique the connection strength was equivalent to over 26 times the peak clinical load. These results indicate that the taper design will provide a connection strength which exceeds the anticipated clinical requirements for the intended of this device.

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

January 7, 2014

IMDS (Innovative Medical Device Systems)
Mr. Andrew Rynearson
Associate Regulatory Counsel
2710 Discovery Drive, Suite 600
Orlando, Florida 32826

Re: K132735
Trade/Device Name: Axia Radial Head System
Regulation Number: 21 CFR 888.3170
Regulation Name: Elbow joint radial (hemi-elbow) polymer prosthesis
Regulatory Class: Class II
Product Code: KWI
Dated: December 4, 2013
Received: December 5, 2013

Dear Mr. Rynearson:

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 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" (21 CFR 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,

Lori A. Wiggins

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

Enclosure

3. Indications for Use Statement

Indications for Use

510(k) Number (if known): ___K132735_____

Device Name: Axia Radial Head System

Indication for Use:

- Radial head replacement for degenerative or post-traumatic disabilities with pain, crepitation, and decreased motion at the radio-humeral and or proximal radio-ulnar joint with:
  - o Joint destruction and/or subluxation
  - o Resistance to conservative treatment
- Primary radial head replacement after fracture
- Symptomatic sequelae after radial head resection
- Revision following failed radial head arthroplasty

CAUTION: This device is intended for uncemented use only.

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

Elizabeth FDA Frank -S

Division of Orthopedic Devices