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skeletal dynamics

510(k) Summary of Safety and Effectiveness
Align Radial Head Arthroplasty System

July 7, 2010

Submitter:
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Contact: Ana M. Escagedo / Vice President Quality & Regulatory Affairs
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FDA Establishment Registration Number: Pending

Trade Name, Common Name, Classification:
Device Trade Name: Align Radial Head System
Device Common or Usual Names: Elbow Hemi Prosthesis, Radial Head
Classification: Class II, 21 CFR 888.3170, Product Code KWI

Predicate Device:
Acumed Anatomic Radial Head System – K041858
Biomet Explore Radial Head – K051385

Description of the Device:
The Align Radial Head System is a radial head prosthesis and instrumentation platform that is designed to orient the radial head perpendicular to the axis of forearm rotation. The fluted plasma coated radial Stem may assist in biological fixation, and is press fit into the medullary canal of the radius. Combined with its unique instrumentation, the ALIGN Radial Head offers the flexibility to adjust the orientation during implantation and restore motion at the radial head, then locks to form a monoblock prosthesis after the optimal implant positioning has been achieved.

The Align Radial Head System is comprised of:

- Multiple sized CoCr Radial Heads with Locking Screw
- Multiple sized titanium alloy Stems, titanium plasma spray coated
- Stainless Steel K-Wires for optimal prosthesis alignment (not to be implanted)
- System specific instrumentation

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Intended Use:
The Align Radial Head System and accessories are designed specifically for:

- 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.

The system is intended for press-fit use.

Technological Characteristics:
The Align Radial Head System has the following similarities to the Anatomic Radial Head System manufactured and distributed by Acumed pursuant to K041858 and by Biomet pursuant to K051383:

- The same indications for use and intended use
- The same basic shape
- Utilize the same materials
- Use the same operating principals

Biocompatibility:
The materials selected for the Align Radial Head System have a long history of safe use in the orthopedic industry. The materials are Ti-6AL-4V ELI per ASTM F 136-00 and CoCrMo per ASTM F-1537. The Titanium Plasma Spray coating on the stem is similar to that found on other currently marketed orthopedic implant devices.

Summary of Non-Clinical Testing:
The following tests were performed to demonstrate that the Align Radial Head System is safe and effective:

- Fatigue and static tests were performed in various positions to evaluate the performance of the device and its mechanical connections.
- Cadaver studies were performed to confirm the repeatability of the surgical procedure. Conclusion:

We believe the subject device is substantially equivalent to the predicate device and conclude that the subject device is as safe and effective as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

AUG 03 2010

Skeletal Dynamics, LLC.
% Orchid Design
% Mr. Joseph Azary
80 Shelton Technology Center
Shelton, Connecticut 06484

Re: K092721
Trade/Device Name: Align 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 26, 2010
Received: July 28, 2010

Dear Mr. Azary:

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.

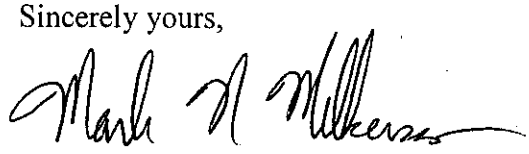
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,



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

Enclosure

K092721 AUG 03 2010

Indications for Use

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510(k) Number (if known): K092721

Device Name: Align Radial Head System

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- Symptomatic sequelae after radial head resection.
- Revision following failed radial head arthroplasty.

The system is intended for press-fit use.

Prescription Use ___X___ (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)

Janette Fa for mxm

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K092721