December 22, 2017
Skeletal Dynamics, LLC
Ana Escagedo
President
8905 SW 87 Avenue, Suite 201
Miami, Florida 33176

Re: K172688
Trade/Device Name: Align 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: November 17, 2017
Received: November 22, 2017

Dear Ana Escagedo:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Vincent J. Devlin -S

for

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172688

Device Name
ALIGN Radial Head System

Indications for Use *(Describe)*
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:
  - o Joint destruction and/or subluxation,
  - o 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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

September 5, 2017

Submitter:
Skeletal Dynamics, LLC
8905 SW 87 Avenue
Suite 201
Miami, FL 33176
Tel: (305) 596-7585
Fax: (305) 596-7591
Contact: Ana M. Escagedo, Vice President
Email: aescagedo@skeletaldynamics.com

Establishment Registration Number: 3006742481

Name and Classification:

Name	Align Radial Head System
Common Name	Elbow Hemi Prosthesis, Radial Head
Classification	21 CFR §888.3170
Product Code	KWI
Class	Class II

Predicate Devices:
Align Radial Head System (K092721)

Description of the Device:
The Align Radial Head System is a radial head prosthesis and instrumentation platform that is designed 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. Combined with its unique instrumentation, the Align Radial Head System offer 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
- System specific instrumentation.

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 substantial equivalence of the Align Radial Head System to the predicate device is demonstrated by similarities in intended use, indications for use, materials, design (fundamental scientific technology), performance, sterility and packaging, and does not present any new issues of safety or effectiveness.

Performance Testing:
Preclinical analysis and testing demonstrated that the Align Radial Head System is substantially equivalent to the predicate device currently marketed. Mechanical and characterization testing which established equivalency included static, shear and abrasion testing. Therefore, the subject device is as safe and effective as legally marketed predicate devices.

Conclusion:
The Skeletal Dynamics Align Radial Head System is substantially equivalent to the predicate device identified in this premarket notification.