Skeletal Dynamics Inc
Alexandra Rodriguez Rojas
Regulatory Affairs Manager
7300 North Kendall Drive
Miami, Florida 33156

September 28, 2023

Re: K231188
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: August 31, 2023
Received: September 1, 2023

Dear Alexandra Rodriguez Rojas:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Farzana Sharmin -S

Digitally signed by Farzana Sharmin -S
Date: 2023.09.28 09:48:20 -04'00'

Farzana Sharmin
Assistant Director
DHT6A: Division of Joint Arthroplasty Devices
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Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K231188

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) SUMMARY
Skeletal Dynamic's
ALIGN Radial Head System

Submitter
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Contact Person: Alexandra Rodriguez Rojas
Date Prepared: August 31, 2023

Name and Classification
Trade Name: Align Radial Head System
Common Name: Elbow Hemi Prosthesis, Radial Head
Classification Name: Elbow joint radial (hemi-elbow) polymer prosthesis
Classification Number: 21 CFR §888.3170
Regulatory Class: Class II
Product Code: KWI

Predicate Devices
Align Radial Head System (K172688)
Reference Devices
Align Radial Head System (K092721)

Device Description

The subject Align Radial Head System and the predicate Align Radial Head System (K172688) are a radial head prosthesis and instrumentation platform that is designed to orient the radial head perpendicular to the axis of forearm rotation. It consists of cobalt chrome modular heads in different sizes with cobalt chrome locking screws, titanium alloy stems, necks, and specialized instrumentation.

Indications for 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.

The device has the same intended use and indications for use as the Company's predicate Align Radial Head System (K172688). Thus, the Align Radial Head System satisfies the first criterion for substantial equivalence.

Summary of Technological Characteristics

The technological characteristics of the Align Radial Head System are substantially equivalent to the predicate device as 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. Both, the subject and predicate Align Radial Head Systems are designed to orient the radial head perpendicular to the axis of forearm rotation. Both consist of cobalt chrome modular heads in different sizes with cobalt chrome locking screws, titanium alloy stems, necks, and specialized instrumentation. The only technological difference between the predicate and subject Align Radial Head System is the new radial head and stem sizes.

Performance Testing

Mechanical testing which established equivalency included static and fatigue compression testing. Based on the verification results, the subject device is as safe and effective as the legally marketed predicate Align Radial Head System (K172688).

Conclusions

The Skeletal Dynamic's Align Radial Head System is substantially equivalent to the predicate device identified in this premarket notification.