November 1, 2024

Skeletal Dynamics Inc
Alexandra Rodriguez
Regulatory Affairs Manager
7300 N Kendall Dr
Miami, Florida 33156

Re: K243381
Trade/Device Name: Total Wrist Arthroplasty System (TWA)
Regulation Number: 21 CFR 888.3800
Regulation Name: Wrist joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWJ
Dated: October 28, 2024
Received: October 30, 2024

Dear Alexandra Rodriguez:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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: 2024.11.01 23:28:56 -04'00'

Farzana Sharmin, PhD
Assistant Director
DHT6A: Division of Joint Arthroplasty Devices
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243381

Device Name

Total Wrist Arthroplasty System (TWA)

Indications for Use *(Describe)*

The Skeletal Dynamics Total Wrist Arthroplasty System is intended for replacement of the painful wrist joint due to rheumatoid arthritis, osteo-arthritis, or post-traumatic arthritis.

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.

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510(k) SUMMARY
Skeletal Dynamic's
Total Wrist Arthroplasty System

Submitter
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Miami, FL 33156
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Facsimile: 305-596-7591
E-mail: arodriguez@seletaldynamics.com
Contact Person: Alexandra Rodriguez Rojas
Date Prepared: November 01, 2024

Name and Classification
Trade Name: Total Wrist Arthroplasty System
Common Name: Prosthesis, Wrist, 3 Part Metal-Plastic-Metal Articulation, Semi-Constrained
Classification Name: Wrist joint metal/polymer semi-constrained cemented prosthesis
Classification Number: 21 CFR §888.3800
Regulatory Class: Class II
Product Code: JWJ

Predicate Devices
Total Wrist Arthroplasty System (K233574)

Device Description

The subject Total Wrist Arthroplasty System is a total joint replacement of the wrist. The system has four major components: a radial component, a carpal component, a poly "lunate" component, and screws which fix the carpal component to the carpus.

Indications for Use

The Skeletal Dynamics Total Wrist Arthroplasty System is intended for replacement of the painful wrist joint due to rheumatoid arthritis, osteo-arthritis, or post-traumatic arthritis.

Summary of Technological Characteristics

The subject Total Wrist Arthroplasty System is a total joint replacement of the wrist. The system has four major components: a radial component, a carpal component, a poly "lunate" component, and screws which fix the carpal component to the carpus.

Each component is sterilized using ethylene oxide gas. The radial and carpal components are made of cobalt chrome (CoCr), with the radial component featuring commercially pure titanium (CPTi) coating. The lunate component is made of highly crosslinked UHMWPE and blended with Vitamin E. The screws are made from Ti 6AL-4V ELI.

Comparison of Technological Characteristics with the Predicate Device

The purpose of this submission is to introduce new sterilization cycles to the subject device. The subject Total Wrist Arthroplasty System is substantially equivalent to the predicate Total Wrist Arthroplasty System. There are no differences in technological characteristics.

Performance Testing

Single Lot sterilization validation was performed using ANSI/AAMI/ISO 11135, Annex E for the TWA metal components. Q-Sterile adoption was performed for the lunate components using ANSI/AAMI/ISO 11135 and EO residual testing per ISO10993-7.

Based on the verification results, the subject device is substantially equivalent to the predicate Total Wrist Arthroplasty System (TWA) (K233574).

Conclusions

The Skeletal Dynamic's Total Wrist Arthroplasty System is substantially equivalent to the predicate device identified in this premarket notification.