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

July 3, 2024

Re: K233574
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: June 4, 2024
Received: June 4, 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.

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: 2024.07.03 13:48:57 -04'00'

Farzana Sharmin, Ph.D.
Assistant Director
DHT6A: Division of Joint Arthroplasty Devices
OHT6: Office of Orthopedic Devices
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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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K233574

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.

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

Submitter

Skeletal Dynamics, Inc.
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Suite 800
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E-mail: arodriguez@seletaldynamics.com
Contact Person: Alexandra Rodriguez Rojas
Date Prepared: July 2, 2024

Name and Classification

Trade Name: Total Wrist Arthroplasty System (TWA)
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

Avanta Orthopaedics, Inc- Wrist Implant (K021859)

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 subject Total Wrist Arthroplasty System is substantially equivalent to the predicate Stryker Remotion Total Wrist Arthroplasty System. Both systems replace a painful, arthritic wrist joint with a metallic and UHMWPE articulating couple. Both systems are semi-constrained. Both systems consist of the same types of components, i.e., a radial stem, a polymeric articulating couple, a carpal component, and screws.

The primary difference is the shape of the articulation geometry, which is spherical for the subject device and ellipsoidal for the predicate. The predicate device uses CoCr non-locking bone screws, while the subject device uses Ti 6AL-4V ELI locking bone screws. The subject device uses a highly cross-linked, Vitamin E stabilized UHMWPE (VEPE) on the articulating component while the predicate uses conventional UHMWPE.

These differences do not raise different questions of safety and effectiveness as demonstrated by the performance testing results and supportive justification.

Performance Testing

Mechanical testing which established equivalency included Subluxation, Wear testing, Compressive Fatigue Testing, Disassociation Testing, Screw Testing, and Impingement Evaluation using the following standards:

- ASTM F1820-13 Standard Test Method for Determining the Forces for Disassembly of Modular Acetabular Devices
- ASTM F732-17 Standard Test Method for Wear Testing of Polymeric Materials Used in Total Joint Prostheses
- ASTM F2025-06 Standard Practice for Gravimetric Measurement of Polymeric Components for Wear Assessment
- ASTM F1223-20 Standard Test Method for Determination of Total Knee Replacement Constraint
- ASTM F1357-14 - Standard Specification for Articulating Total Wrist Implants
- ASTM F382-17 – Standard Specification and Test Method for Metallic Bone Plates
- ASTM F543-23 – Standard Specification and Test Methods for Metallic Medical Bone Screws
- ASTM F2695-12 – Standard Specification for Ultra-High Molecular Weight Polyethylene Powder Blended with Alpha-Tocopherol (Vitamin E) and Fabricated Forms for Surgical Implant Applications
- ISO-14242-1 - Implants for surgery — Wear of total hip-joint prostheses. Loading and displacement parameters for wear-testing machines and corresponding environmental conditions for test

Based on the verification results and supportive justification, the subject device is substantially equivalent to the predicate Avanta Orthopaedics, Inc, Wrist Implant (K021859).

Conclusions

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