Ascension Orthopedics, Inc.
Stephanie Rincones
Regulatory Affairs Specialist
11101 Metric Blvd.
Austin, Texas 78758

May 30, 2024

Re: K233674
Trade/Device Name: Freedom Wrist Arthroplasty System
Regulation Number: 21 CFR 888.3800
Regulation Name: Wrist joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWJ
Dated: May 1, 2024
Received: May 1, 2024

Dear Stephanie Rincones:

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: 2024.05.30 16:27:17 -04'00'

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

Submission Number *(if known)*

K233674

Device Name

Freedom Wrist Arthroplasty System

Indications for Use *(Describe)*

The Freedom Wrist Arthroplasty System is indicated for intractable pain resulting from traumatic arthritis, osteoarthritis, rheumatoid arthritis, and trauma-induced osteoarthritis of the radial/carpal joint and is intended to replace functionality of the joint due to deformity or elements stated above. The Freedom Wrist Arthroplasty System is intended for cemented 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.

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510(k) Summary

Prepared on: 2023-11-15

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Ascension Orthopedics, Inc.
Applicant Address	11101 Metric Blvd. Austin TX 78758 United States
Applicant Contact Telephone	737-270-8239
Applicant Contact	Ms. Stephanie Rincones
Applicant Contact Email	Stephanie.Rincones@smith-nephew.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Freedom Wrist Arthroplasty System
Common Name	Wrist Prosthesis
Classification Name	Wrist joint metal/polymer semi-constrained cemented prosthesis
Regulation Number	21 CFR 888.3800
Product Code	JWJ, Prosthesis, Wrist, 3 Part Metal-Plastic-Metal Articulation, Semi-Cons

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K132250	Integra Freedom Wrist Arthroplasty System	JWJ

Device Description Summary

21 CFR 807.92(a)(4)

The Freedom Wrist Arthroplasty System consists of components to replace the articulation of the distal radius and proximal row of carpal bones of the wrist joint. The components are intended to be implanted together as a system, not individually as hemi-arthroplasty components. The radial component is made of Cobalt Chrome Molybdenum Alloy (CrCoMo) and has a concave articulating surface and is fixed by means of a stem which is inserted and cemented into the radial intramedullary canal. The carpal implant is an assembly consisting of a titanium carpal plate, which is fixed into the carpal bones with a cemented central peg and two titanium screws and locking caps. A convex Ultra-High-Molecular-Weight Polyethylene (UHMWPE) bearing is locked onto the carpal plate to articulate with the radial component.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Freedom Wrist Arthroplasty System is indicated for intractable pain resulting from traumatic arthritis, osteoarthritis, rheumatoid arthritis, and trauma-induced osteoarthritis of the radial/carpal joint and is intended to replace functionality of the joint due to deformity or elements stated above. The Freedom Wrist Arthroplasty System is intended for cemented use.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The subject device has the same intended use and indications for use as the predicate device.

Technological Comparison

21 CFR 807.92(a)(6)

The subject device introduces MR conditional labeling when compared to the predicate. Otherwise, the subject device has the same

technological characteristics as the predicate device.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Safety and compatibility in the magnetic resonance (MR) environment was established through non-clinical testing that addressed applicable MR safety hazards per ASTM F2503 (Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment) and FDA Guidance (Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment). Testing addressed the following: Magnetically Induced Displacement Force (ASTM F2052), Magnetically Induced Toque (ASTM F2213), RF-Induced Heating (ASTM F2182), and Image Artifacts (ASTM F2119).

Non-clinical testing supports the addition of MR Conditional labeling to the subject device by demonstrating that it can be safely scanned under defined conditions that are clinically relevant.