March 11, 2022

Smith & Nephew, Inc.
Stephanie Rincones
Regulatory Affairs Specialist
11101 Metric Blvd
Austin, Texas 78758

Re: K213827
Trade/Device Name: TITAN Total Shoulder System (TSS), TITAN Reverse Shoulder System (RSS), TITAN Humeral Resurfacing Arthroplasty System (HRA), Modular Radial Head System (MRH), Katalyst Bipolar Radial Head System (Katalyst)
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder Joint Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: KWS, HSD, PHX, KWI
Dated: February 9, 2022
Received: February 10, 2022

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 (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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; 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 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,

Lixin Liu, Ph.D.
Acting 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213827

Device Name
TITAN Total Shoulder System

Indications for Use *(Describe)*

The TITAN Modular Total Shoulder System is indicated for use as a hemi or total shoulder replacement for:
• Severely painful and/or disabled joint resulting from osteoarthritis, traumatic arthritis or rheumatoid arthritis.
• Fracture-dislocations of the proximal humerus where the articular surface is severely comminuted, separated from its blood supply or where the surgeon's experience indicates that alternative methods of treatment are unsatisfactory.
• Other difficult clinical problems where shoulder arthrodesis or resection arthroplasty are not acceptable (e.g. revision of a failed primary component).

Shoulder Hemiarthroplasty is also indicated for:
• Ununited humeral head fractures.
• Avascular necrosis of the humeral head.
• Rotator cuff arthropathy.
• Deformity and/or limited motion.

The humeral component is intended for cemented or uncemented use. The glenoid component is intended for cemented use only.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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.

510(k) Number *(if known)*
K213827

Device Name
TITAN Reverse Shoulder System

Indications for Use *(Describe)*
The TITAN Reverse Shoulder System is indicated for use in a grossly deficient rotator cuff joint with severe arthropathy or a previously failed joint replacement with a grossly deficient rotator cuff joint. The patient's joint must be anatomically and structurally suited to receive the selected implants and a functional deltoid muscle is necessary to use the device. The Titan Reverse Shoulder System is indicated for primary, fractures including proximal humeral, or revision total shoulder replacement for the relief of pain and significant disability due to gross rotator cuff deficiency. The glenoid baseplate is intended for cementless application with the addition of screws for fixation. The humeral stem is indicated for cemented or uncemented use and the humeral body component is intended for cementless 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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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.

510(k) Number *(if known)*
K213827

Device Name
TITAN Humeral Resurfacing Arthroplasty System

Indications for Use *(Describe)*
The Ascension HRA System is intended for resurfacing of the humeral head due to:
- Patients disabled by either non-inflammatory or inflammatory arthritis (i.e. rheumatoid arthritis, osteoarthritis and avascular necrosis)
- Mild or moderate humeral head deformity and/or limited motion
- Post-traumatic arthritis
- Malunions of the humeral head
- Acute fractures of the humeral head
- Patients with an intact or reparable rotator cuff

Contraindications:
- Infection, sepsis, and osteomyelitis
- Osteoporosis
- Metabolic disorders which may impair bone formation
- Osteomalacia
- Rapid joint destruction, marked bone loss or bone resorption apparent on roentgenogram
- Revision procedures where other devices or treatments have failed

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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.

510(k) Number *(if known)*
K213827

Device Name
Modular Radial Head System

Indications for Use *(Describe)*
The Ascension Modular Radial Head is intended 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 or subluxation visible on x-ray
  - resistance to conservative treatment
• Primary replacement after fracture of the radial head
• Symptomatic sequelae after radial head resection
• Revision following failed radial head arthroplasty

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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.

510(k) Number *(if known)*
K213827

Device Name
Katalyst Bipolar Radial Head System

Indications for Use *(Describe)*
The Katalyst Radial Head system is generally indicated for use in radial head replacement arthroplasty.

Use of the implant is contraindicated in those cases where complete avascular necrosis has rendered bone stock inadequate.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

SmithNephew

510(k) Summary

Date	March 11, 2022
Submitter	Ascension Orthopedics, Inc. 11101 Metric Blvd. Austin, TX 78758
Point of Contact	Stephanie Rincones Regulatory Affairs Specialist 11101 Metric Blvd. Austin, TX 78758 *737-270-8239*
Review Panel	Orthopedic
Trade Name	**1.** TITAN Total Shoulder System (TSS) **2.** TITAN Reverse Shoulder System (RSS) **3.** TITAN Humeral Resurfacing Arthroplasty System (HRA) **4.** Modular Radial Head System (MRH) **5.** Katalyst Bipolar Radial Head System (Katalyst)
Common Name	**1.** Prosthesis, Shoulder, Semi-Constrained, Metal/Polymer Cemented Prosthesis, Shoulder, Hemi-, Humeral, Metallic Uncemented **2.** Shoulder Prosthesis, Reverse Configuration **3.** Prosthesis, Shoulder, Hemi-, Humeral, Metallic Uncemented **4.** Prosthesis, Elbow, Hemi-, Radial, Polymer **5.** Prosthesis, Elbow, Hemi-, Radial, Polymer
Product Code, Classification Name (Regulation)	**1.** KWS, Shoulder joint metal/polymer semi-constrained cemented prosthesis (21 CFR 888.3660) HSD, Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis (21 CFR 888.3690) **2.** PHX, Shoulder joint metal/polymer semi-constrained cemented prosthesis (21 CFR 888.3660) **3.** HSD, Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis (21 CFR 888.3690) **4.** KWI, Elbow joint radial (hemi-elbow) polymer prosthesis (21 CFR 888.3170) **5.** KWI, Elbow joint radial (hemi-elbow) polymer prosthesis (21 CFR 888.3170)
Classification	Class II
Predicate Device	Primary Predicate: **1.** K142413 – TSS (Line Extension) Additional Predicates: **1.** K100448 – TSS (Original) K112438 – TSS (Line Extension) K152047 – TSS (Line Extension) **2.** K161189 – RSS (Indication Add) K173717 – RSS (Design Change) K181999 – RSS (Line Extension) K190588 – RSS (Line Extension) **3.** K062861 – HRA **4.** K032686 – MRH **5.** K032806 – Katalyst
Device Description	The purpose of this submission is the addition of MR Conditional information to the labeling of the predicate devices. There are no other changes proposed in this submission. The following aspects of the devices are not impacted by the additional labeling and remain identical to the predicate devices as cleared in their respective 510(k)s. • Intended Use/Indications for Use • Contraindications • Design and Dimensions • Performance Specifications • Materials • Biocompatibility

510(k) Summary

Intended Use/ Indications for Use	**1.** The TITAN Modular Total Shoulder System is indicated for use as a hemi or total shoulder replacement for: • Severely painful and/or disabled joint resulting from osteoarthritis, traumatic arthritis or rheumatoid arthritis. • Fracture-dislocations of the proximal humerus where the articular surface is severely comminuted, separated from its blood supply or where the surgeon's experience indicates that alternative methods of treatment are unsatisfactory. • Other difficult clinical problems where shoulder arthrodesis or resection arthroplasty are not acceptable (e.g., revision of a failed primary component). Shoulder Hemiarthroplasty is also indicated for: • Ununited humeral head fractures. • Avascular necrosis of the humeral head. • Rotator cuff arthropathy. • Deformity and/or limited motion. The humeral component is intended for cemented or uncemented use. The glenoid component is intended for cemented use only. **2.** The TITAN Reverse Shoulder System is indicated for use in a grossly deficient rotator cuff joint with severe arthropathy or a previously failed joint replacement with a grossly deficient rotator cuff joint. The patient's joint must be anatomically and structurally suited to receive the selected implants and a functional deltoid muscle is necessary to use the device. The Titan Reverse Shoulder System is indicated for primary, fractures including proximal humeral, or revision total shoulder replacement for the relief of pain and significant disability due to gross rotator cuff deficiency. The glenoid baseplate is intended for cementless application with the addition of screws for fixation. The humeral stem is indicated for cemented or uncemented use and the humeral body component is intended for cementless use. **3.** The Ascension HRA System is intended for resurfacing of the humeral head due to: • Patients disabled by either non-inflammatory or inflammatory arthritis (i.e., rheumatoid arthritis, osteoarthritis and avascular necrosis) • Mild or moderate humeral head deformity and/or limited motion • Post-traumatic arthritis • Malunions of the humeral head • Acute fractures of the humeral head • Patients with an intact or reparable rotator cuff Contraindications: • Infection, sepsis, and osteomyelitis • Osteoporosis • Metabolic disorders which may impair bone formation • Osteomalacia • Rapid joint destruction, marked bone loss or bone resorption apparent on roentgenogram • Revision procedures where other devices or treatments have failed **4.** The Ascension Modular Radial Head is intended 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 or subluxation visible on x-ray - resistance to conservative treatment • Primary replacement after fracture of the radial head • Symptomatic sequelae after radial head resection • Revision following failed radial head arthroplasty **5.** The Katalyst Radial Head system is generally indicated for use in radial head replacement arthroplasty. Use of the implant is contraindicated in those cases where complete avascular necrosis has rendered bone stock inadequate.
Non-Clinical Performance Data	Non-clinical Magnetic Resonance Imaging (MRI) testing performed on the worst-case devices determined that the devices are MR Conditional in accordance with 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). MRI testing addressed the following: 1. Magnetically Induced Displacement Force (ASTM F2052) 2. Magnetically Induced Toque (ASTM F2213) 3. RF-Induced Heating (ASTM F2182) 4. Image Artifact (ASTM F2119)
Conclusion	The completed MR compatibility testing establishes the conditional safety and compatibility of the passive implant devices in the MR environment, and supports the addition of MR Conditional labeling to the devices.