Smith & Nephew, Inc.
Cassidy Lemkau
Senior Regulatory Affairs Specialist
7135 Goodlett Farms Parkway
Cordova, Tennessee 38016

January 3, 2023

Re: K220847
Trade/Device Name: AETOS Shoulder System
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KWS, HSD, KWT, PHX
Dated: December 5, 2022
Received: December 5, 2022

Dear Cassidy Lemkau:

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,

Farzana Sharmin -S

Digitally signed by Farzana Sharmin -S
Date: 2023.01.03 18:03:53 -05'00'

For Victoria Lilling, M.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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220847

Device Name
AETOS Shoulder System

Indications for Use *(Describe)*

In Anatomic:
The stem and head may be used by themselves, as a hemiarthroplasty, if the natural glenoid provides a sufficient bearing surface, or in conjunction with the glenoid, as a total replacement.

The AETOS Shoulder System is to be used only in patients with an intact or reconstructable rotator cuff, where it is intended to provide increased mobility and stability and to relieve pain. The AETOS Shoulder System is indicated for use as a replacement of shoulder joints disabled by:

- Rheumatoid arthritis
- Non-inflammatory degenerative joint disease
- Correction of functional deformity
- Fractures of the humeral head
- Traumatic arthritis
- Revision of other devices if sufficient bone stock remains

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

In Reverse:
The AETOS Shoulder System is indicated for use as a replacement of shoulder joints for patients with a functional deltoid muscle and with massive and non-repairable rotator cuff-tear with pain disabled by:

- Rheumatoid arthritis
- Non-inflammatory degenerative joint disease
- Correction of functional deformity
- Fractures of the humeral head
- Traumatic arthritis
- Revision of devices if sufficient bone stock remains

The humeral liner component is indicated for use in the AETOS Shoulder System as a primary reverse total shoulder replacement and for use when converting an anatomic AETOS Shoulder System into a reverse shoulder construct. This facilitates the conversion without the removal of the humeral stem during revision surgery for patients with a functional deltoid muscle. The component is permitted to be used in the conversion from anatomic to reverse if the humeral stem is well fixed, the patient has a functional deltoid muscle; the arthroplasty is associated with a massive and non-repairable rotator cuff tear.

The coated humeral stem is indicated for uncemented use. The coated glenoid base plate is intended for cementless application with the addition of screws for fixation.

Note: All implant components are single 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.

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510(k) Summary
AETOS Shoulder System
Traditional 510(k)

Sponsor	Smith & Nephew, Inc. Orthopedic Division 7135 Goodlett Farms Parkway Cordova, Tennessee 38016
Establishment Number	3008744062
Point of Contact	Cassidy Lemkau (Whipple) Senior Regulatory Specialist 512-466-1130
Date	January 3, 2023
Trade Name	AETOS Shoulder System
Common Name	Shoulder Prosthesis
Product Code	**1.** KWS **2.** HSD **3.** KWT **4.** PHX
Regulation	**1.** Shoulder joint metal/polymer semi-constrained cemented prosthesis (21 CFR 888.3660) **2.** Shoulder Joint humeral (hemi-shoulder) metallic uncemented (21 CFR 888.3690) **3.** Shoulder joint metal/polymer non-constrained cemented prosthesis (21 CFR 888.3650) **4.** Shoulder joint metal/polymer semi-constrained cemented prosthesis (21 CFR 888.3660)
Classification	Class II
Predicate Device	Tornier SAS Aequalis Ascend Flex Shoulder System: K122698 (Primary), K151293 Tornier, Inc. Aequalis PerFORM Reversed, Aequalis PerFORM + Reversed Glenoid: K161742 Tornier, Inc. Aequalis PerFORM + Shoulder System: K160975 PROMOS Reverse Shoulder System: K081016

	Titan Modular Total Shoulder System Fin-Lock Glenoid: K152047 Equinoxe Reverse Shoulder System: K063569 Titan Reverse Shoulder System: K181999, K190588,
Reference Device	Titan Modular Total Shoulder System: K142413, K100448 Titan Reverse Shoulder System: K130050 Zimmer Trabecular Metal Reverse Shoulder System: K121543 Zimmer Comprehensive Reverse Shoulder System: K181611
Classification Panel	Orthopedic/87
Device Description	The AETOS Shoulder System consists of: In an anatomic configuration: A humeral stem (Titanium) with a plasma spray coating (Titanium), a compatible humeral head (CoCr) with a compatible glenoid (UHMWPE). The AETOS Shoulder System stem and head may be used by themselves for hemiarthroplasty. In a reverse configuration: A humeral stem (Titanium) with a plasma spray coating (Titanium), a compatible liner (UHMWPE), glenoid baseplate (Titanium with Titanium plasma spray), glenosphere (CoCr with Titanium retaining component), peripheral screws (Titanium), center screw (Titanium), and optional post extension (Titanium with Titanium plasma spray).
Intended Use/ Indications for Use	**Intended Use** The AETOS Shoulder System is intended for: • Replacement of shoulder joints in primary anatomic or primary reverse arthroplasty. • Replacement of shoulder joint devices in revision cases if sufficient bone stock is present. • The AETOS Shoulder System also allows for conversions from anatomic to reverse in case of revision. **Indications for Use** In Anatomic: The stem and head may be used by themselves, as a hemiarthroplasty, if the natural glenoid provides a sufficient bearing surface, or in conjunction with the glenoid, as a total replacement.

	The AETOS Shoulder System is to be used only in patients with an intact or reconstructable rotator cuff, where it is intended to provide increased mobility and stability and to relieve pain. The AETOS Shoulder System is indicated for use as a replacement of shoulder joints disabled by: • Rheumatoid arthritis • Non-inflammatory degenerative joint disease • Correction of functional deformity • Fractures of the humeral head • Traumatic arthritis • Revision of other devices if sufficient bone stock remains The coated humeral component is intended for uncemented use. The glenoid component is intended for cemented use only. In Reverse: The AETOS Shoulder System is indicated for use as a replacement of shoulder joints for patients with a functional deltoid muscle and with massive and non-repairable rotator cuff-tear with pain disabled by: • Rheumatoid arthritis • Non-inflammatory degenerative joint disease • Correction of functional deformity • Fractures of the humeral head • Traumatic arthritis • Revision of devices if sufficient bone stock remains The humeral liner component is indicated for use in the AETOS Shoulder System as a primary reverse total shoulder replacement and for use when converting an anatomic AETOS Shoulder System into a reverse shoulder construct. This facilitates the conversion without the removal of the humeral stem during revision surgery for patients with a functional deltoid muscle. The component is permitted to be used in the conversion from anatomic to reverse if the humeral stem is well fixed, the patient has a functional deltoid muscle; the arthroplasty is associated with a massive and non-repairable rotator cuff tear. The coated humeral stem is indicated for uncemented use. The coated glenoid baseplate is intended for cementless application with the addition of screws for fixation. Note: All implant components are single use.

Nonclinical Performance Data	The AETOS Shoulder System has undergone the following testing: • Full Construct Fatigue Testing (Anatomic and Reverse Configurations) • Taper Axial Testing (Humeral Head, Glenosphere) • Taper Torsional Testing (Humeral Head, Glenosphere) • Anatomic Glenoid Pull-out Testing • Anatomic Glenoid Loosening Testing • Humeral Liner Axial Disassembly Testing • Humeral Liner Torsional Disassembly Testing • Humeral Liner Lever-out Testing • Screw Testing (Torsional Properties, Axial Pullout) • Reverse Glenoid Dynamic Loosening Testing • Post Extension Corrosion Testing • Scapular Notching Risk Evaluation • Range of Motion Evaluation • Wear Assessment
Clinical Performance Data	Clinical performance data were not necessary to demonstrate substantial equivalence of the subject device.
Conclusion	Substantial equivalence of the AETOS Shoulder System to cited predicates can be demonstrated based on the following: • The subject and predicate devices have similar intended use and indications for use. • The subject and predicate devices share similar functional and technological characteristics via the same operational principles. Per this comparison and the results of bench testing it can be concluded any differences between the subject and predicate devices do not raise different questions of safety and effectiveness. Therefore, the AETOS Shoulder System is substantially equivalent to the cited predicates.