



November 20, 2024

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

Re: K240716

Trade/Device Name: AETOS Shoulder System Stemless Humeral Prosthesis
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PKC, KWS, KWT, HSD, PHX
Dated: October 22, 2024
Received: October 23, 2024

Dear Cassidy Whipple:

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: 2024.11.20
15:37:30 -05'00'

Farzana Sharmin, PhD
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

Indications for Use

Submission Number (if known)

K240716

Device Name

AETOS Shoulder System Stemless Humeral Prosthesis

Indications for Use (Describe)

In Anatomic:

The AETOS Shoulder System (when used with the AETOS Humeral Meta Stems) 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 humeral stems (AETOS Humeral Meta Stems) 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. When used with the AETOS Humeral Meta Stems, 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 AETOS Shoulder System (when used with AETOS Stemless Humeral Prosthesis) is to be used only in patients with an intact or reconstructable rotator cuff.

When used with AETOS Stemless Humeral Prosthesis, the AETOS Shoulder System is indicated for anatomic total shoulder replacement of shoulder joints disabled by:

- Non-inflammatory degenerative joint disease
- Traumatic arthritis
- Revision of other devices if sufficient bone stock remains

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

In Reverse:

The AETOS Shoulder System, when used with AETOS Humeral Meta Stems, 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 stems are 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.

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
PRASStaff@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."

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

Sponsor	Smith & Nephew, Inc. Orthopedic Division 7135 Goodlett Farms Parkway Cordova, Tennessee 38016
Establishment Number	3008744062
Point of Contact	Cassidy Whipple Senior Regulatory Specialist 737-270-8220
Date	November 19, 2024
Trade Name	AETOS Shoulder System Stemless Humeral Prosthesis
Common Name	Shoulder Prosthesis
Product Code	PKC (primary), KWS, HSD, KWT, 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)
Classification	Class II
Predicate Devices	Smith & Nephew AETOS Shoulder System: K220847 (Primary) Simpliciti Shoulder System: K143552
Classification Panel	Orthopedic
Device Description / Intended Use	The AETOS Stemless Humeral Prosthesis subject to this submission is a humeral anchor intended for press-fit fixation as part of an implant construct in anatomic total shoulder arthroplasty for the treatment of skeletally mature individuals with degenerative diseases of the glenohumeral joint.
Indications for Use (System)	In Anatomic: The AETOS Shoulder System (when used with the AETOS Humeral Meta Stems) 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 humeral stems (AETOS Humeral Meta Stems) 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. When used with the AETOS Humeral Meta Stems, 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 AETOS Shoulder System (when used with AETOS Stemless Humeral Prosthesis) is to be used only in patients with an intact or reconstructable rotator cuff.

When used with AETOS Stemless Humeral Prosthesis, the AETOS Shoulder System is indicated for anatomic total shoulder replacement of shoulder joints disabled by:

- Non-inflammatory degenerative joint disease
- Traumatic arthritis
- Revision of other devices if sufficient bone stock remains

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

In Reverse:

The AETOS Shoulder System, when used with AETOS Humeral Meta Stems, 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 stems are 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.
Nonclinical Performance Data	• Construct fatigue and corrosion resistance assessment • Post-fatigue stability • Static disengagement • Dynamic stability / loosening • Bone volume and contact analysis
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 Stemless Humeral Prosthesis to cited predicates can be demonstrated based on the following: • The subject and predicate devices have the same intended use and similar Indications for Use. • The subject and predicate devices share similar functional and technological characteristics via the same operational principles. • The subject and predicate devices are made from the same materials and packaged and sterilized using the same methods. Bench testing supports that any differences between subject and predicate devices do not introduce or exacerbate any different questions of safety or effectiveness. As a result Smith & Nephew concludes the subject AETOS Shoulder System Line Extensions are substantially equivalent to cited predicate device.