



June 7, 2023

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

Re: K230572

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: May 10, 2023

Received: May 10, 2023

Dear Patrick Hughes:

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,

Joseph P.

Russell -S

Digitally signed by Joseph P.
Russell -S
Date: 2023.06.07 15:52:32
-04'00'

For: Farzana Sharmin, 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

Indications for Use

510(k) Number (*if known*)
K230572

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 baseplate 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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Section 5 - 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	Patrick Hughes Senior Regulatory Specialist 352-359-7940
Date	June 5, 2023
Trade Name	AETOS Shoulder System
Common Name	Shoulder Prosthesis
Product Code	<ol style="list-style-type: none"> 1. KWS 2. HSD 3. KWT 4. PHX
Regulation	<ol style="list-style-type: none"> 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 Devices	Smith & Nephew AETOS Shoulder System: K220847 (Primary) Tornier, Inc. PERFORM Humeral System - Stem: K201315 LimaCorporate SMR TT Augmented Glenoid System: K200171
Reference Devices	Encore AltiVate Reverse Humeral Stem, AltiVate Reverse Small Spacer, AltiVate Reverse, Small Hemi-Adapter, AltiVate Reverse, Small Socket Insert: K172351 Zimmer Trabecular Metal Reverse Shoulder System: K052906 Univers Revers Shoulder Prosthesis System: K130129

	<p>LimaCorporate Bone Screws dia. 5,0 mm: K210717</p> <p>LimaCorporate SMR 40mm Glenosphere: K142139</p> <p>Titan Reverse Shoulder System: K130050</p> <p>Titan Reverse Shoulder System: K181999</p> <p>Titan Modular Total Shoulder System Fin-Lock Glenoid: K152047</p>
Classification Panel	Orthopedic
Device Description	<p>The AETOS Shoulder System consists of:</p> <p>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.</p> <p>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), optional humeral spacer (Titanium), and optional post extension (Titanium with Titanium plasma spray).</p>
Intended Use/	<p>The AETOS Shoulder System is intended for:</p> <ul style="list-style-type: none"> • 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	<p>In Anatomic:</p> <p>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.</p> <p>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:</p> <ul style="list-style-type: none"> • Rheumatoid arthritis • Non-inflammatory degenerative joint disease

	<ul style="list-style-type: none"> • Correction of functional deformity • Fractures of the humeral head • Traumatic arthritis • Revision of other devices if sufficient bone stock remains <p>The coated humeral component is intended for uncemented use. The glenoid component is intended for cemented use only.</p> <p>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:</p> <ul style="list-style-type: none"> • 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 <p>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.</p> <p>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.</p> <p>Note: All implant components are single use.</p>
Nonclinical Performance Data	<ul style="list-style-type: none"> • Construct fatigue • Dynamic glenoid loosening / dissociation per ASTM F2028 • Range of motion evaluation • Scapular notching evaluation • Construct disassembly evaluation • Total humeral offset evaluation

Clinical Performance Data	Clinical performance data were not necessary to demonstrate substantial equivalence of the subject device.
Technological Similarities and Differences Compared to Predicate	<p>The subject submission represents line extensions to the AETOS Shoulder System as follows:</p> <p><i>AETOS +15 Full Wedge Baseplates</i> AETOS +15 Full Wedge Baseplates have the same intended use as predicate AETOS baseplates: to resurface glenoid bone as part of reverse total shoulder arthroplasty. Like predicate AETOS baseplates, AETOS +15 Full Wedge Baseplates are manufactured from Ti6Al4V and have an unalloyed titanium plasma spray coating as well as screw and post features for uncemented fixation. Like all AETOS baseplates, AETOS +15 Full Wedge Baseplates mate with compatible glenospheres via peripheral taper. AETOS +15 Full Wedge Baseplates have the same centered configuration, diameter, screw-hole configuration, and post extension compatibility as predicate augmented AETOS baseplates but differ in that they provide an additional five degrees of augmentation. AETOS +15 Full Wedge Baseplate components use packaging configurations and sterilization processes identical to cited predicates.</p> <p><i>AETOS 38mm +3mm Eccentric Glenospheres</i> AETOS 38mm +3mm Eccentric Glenospheres have the same intended use as predicate AETOS glenospheres: to provide a spherical surface for articulation with AETOS Shoulder System humeral liners as part of a reverse shoulder implant construct. Like predicate AETOS glenospheres, AETOS 38mm +3mm Eccentric Glenospheres are manufactured from CoCrMo and attach to compatible baseplates with a retainer and screw manufactured from Ti6Al4V. AETOS 38mm +3mm Eccentric Glenospheres have the same articulating radius, lateralization, and eccentricity as predicate AETOS 42mm +3mm Eccentric Glenospheres but differ in that they feature a smaller diameter. AETOS 38mm +3mm Eccentric Glenospheres use packaging configurations and sterilization processes identical to cited predicates.</p> <p><i>AETOS Reverse Humeral Spacers</i> AETOS Reverse Humeral Spacers have the same intended use as predicate and reference humeral spacers: to provide a method for lateralizing reverse shoulder arthroplasty implant constructs on the humeral side by introducing additional material between humeral stems and humeral liners. Like predicate Tornier PerFORM humeral</p>

	<p>spacers, AETOS Reverse Humeral Spacers are manufactured from Ti-6Al-4V, provide 9mm of thickness, are available in two sizes, and mate with compatible stems via Morse taper. AETOS Reverse Humeral Spacers differ from predicate and reference devices in that compatibility with humeral stems on the distal aspect and compatibility with humeral liners on the proximal aspect require connection geometry specific to their respective systems. Like predicate Tornier PerFORM humeral spacers, AETOS Reverse Humeral Spacers are provided sterile via gamma irradiation.</p>
Conclusion	<p>Substantial equivalence of the AETOS Shoulder System to cited predicates can be demonstrated based on the following:</p> <ul style="list-style-type: none">• The subject and predicate devices have the same intended use and similar or the same 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. <p>Bench testing supports that any minor dimensional differences between subject and predicate devices do not introduce or exacerbate any potential issues of safety and effectiveness. As a result Smith & Nephew concludes the subject AETOS Shoulder System Line Extensions are substantially equivalent to cited predicate devices.</p>