July 1, 2026

Restor3D
Knox Pittman
Regulatory Engineer
4001 Nc-54 Hwy.
Suite 2160
Durham, North Carolina 27709

Re: K260556
Trade/Device Name: Veritas Shoulder System
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PHX, HSD
Dated: June 3, 2026
Received: June 4, 2026

Dear Knox Pittman:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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

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

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)*

K260556

Device Name

Veritas Shoulder System

Indications for Use *(Describe)*

Reverse Application of the Veritas Shoulder System:
The Veritas Shoulder System is indicated for use in patients whose shoulder joint has a grossly deficient rotator cuff with severe arthropathy and/or previously failed shoulder joint replacement with a grossly deficient rotator cuff. The patient must be anatomically and structurally suited to receive the implants and a functional deltoid muscle is necessary.
The Veritas Reverse Total Shoulder System standard components are indicated for primary, fracture, or revision total shoulder replacement for the relief of pain and significant disability due to gross rotator cuff deficiency. The Veritas system's patient specific components are only indicated for primary total shoulder replacement.
Glenoid component with porous surface is indicated for uncemented application with the addition of screw fixation.
Note: A CT scan is used to create the Veritas patient specific components

Hemiarthroplasty Application of the Veritas Shoulder System:
The Veritas Shoulder System is indicated for:
• Advanced wear and tear of the shoulder joint resulting from degenerative, post-traumatic, or rheumatoid arthritis if adequate bone stock is present.
• Avascular Necrosis
• Conditions consequent to earlier operations
Humeral components with porous surface are indicated for either cemented or uncemented applications.

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.

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"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."

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510(k) Summary

Date Prepared: July 1, 2026

This 510(k) Summary is being submitted in accordance with the requirements of 21 CFR 807.92.

A. 510(k) Owner:

restor3d, inc.
4001 NC-54 Hwy, Suite 3160
Durham, NC 27709

B. Primary Correspondent:

Knox Pittman
Regulatory Affairs Specialist II
knox.pittman@restor3d.com

C. Premarket Notification:

Submission Type:	Traditional 510(k)
Trade Name:	Veritas Shoulder System
Classification Name:	Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulation Number:	888.3660
Product Code:	PHX, HSD
Classification:	II
Review Panel:	Orthopedic

D. Indications for Use:

Reverse Application of the Veritas Shoulder System:

The Veritas Shoulder System is indicated for use in patients whose shoulder joint has a grossly deficient rotator cuff with severe arthropathy and/or previously failed shoulder joint replacement with a grossly deficient rotator cuff. The patient must be anatomically and structurally suited to receive the implants and a functional deltoid muscle is necessary.

The restor3d rTSA System is indicated for primary, fracture, or revision total shoulder replacement for the relief of pain and significant disability due to gross rotator cuff deficiency. The patient specific components are only indicated for primary total shoulder replacement.

Glenoid components with porous surface are indicated for uncemented application with the addition of screw fixation.

Note: A CT Scan is used to create the Veritas patient specific components

Hemiarthroplasty Application of the Veritas Shoulder System:

The Veritas Shoulder System is indicated for:

Advanced wear and tear of the shoulder joint resulting from degenerative, post-traumatic, or rheumatoid arthritis if adequate bone stock is present.
Avascular Necrosis
Conditions consequent to earlier operations

Humeral components with porous surface are indicated for either cemented or uncemented applications.

E. Predicate Devices:

The subject Veritas Shoulder System is substantially equivalent to the following devices:

510{k)	Trade Name	Manufacturer
Primary Predicate Device		
K193099	Anatomical Shoulder System	Zimmer Biomet
Reference Device		
K243643	Veritas Shoulder System *Previously cleared as restor3d Reverse Total Shoulder Replacement System*	restor3d
K203375	Revomotion *Previously cleared as OVOMotion Reverse Shoulder Arthroplasty System*	Arthrosurface
K162455	Humelock Reversed Shoulder	Fx Solutions

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F. Device Description:

The Veritas Shoulder System Hemiarthroplasty line extension is an off-the-shelf system designed as a robust shoulder replacement for patients with glenoid and/or humeral bone defects. The subject components include the adaptor plate and the anatomic humeral head. The subject components are designed to mate with the previously cleared Veritas Shoulder System humeral stem component, cleared via K243643. The subject humeral head is affixed to the humeral stem component via the adapter plate, which features self-locking male tapers both proximally and distally. Additionally, the system includes supporting instrumentation to facilitate the surgical procedure.

G. Substantial Equivalence Comparison

The Veritas Shoulder System Hemiarthroplasty application components, intended use, and indications for use are similar to the predicate device (Zimmer, Anatomical Shoulder System, K193099).

The subject Veritas Shoulder System materials and manufacturing are identical to the reference device, Veritas Shoulder System (K243643).

Differences in design of the subject device compared to the predicate are further supported since the subject Veritas Shoulder System performance is substantially equivalent to the reference devices Arthrosurface Revomotion (K203375) and Fx Solutions Humelock Reversed Shoulder (K162455).

H. Comparison of Performance

The subject Veritas Shoulder System was subject to the following non-clinical performance tests to support the assertion of substantial equivalence:

- Axial Taper Disassembly Strength per ASTM F2009
- Torsional Taper Disassembly Strength
- Humeral Stem Fatigue
- Fretting and Corrosion

I. Conclusions:

In summary, based on the comparison of indications for use, intended use, and technological characteristics, as well as the performance testing conducted, the subject Veritas Shoulder System is shown to be substantially equivalent to the predicate Zimmer Anatomical Shoulder System (K193099).