May 7, 2026

Restor3d
Brianna Prindle
Director of Regulatory Affairs
4001 Nc-54 Hwy
Suite 2160
Durham, North Carolina 27709

Re: K253992
Trade/Device Name: Veritas Reverse Total 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, QHE
Dated: April 7, 2026
Received: April 7, 2026

Dear Brianna Prindle:

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253992

Please provide the device trade name(s).

Veritas Reverse Total Shoulder System

Please provide your Indications for Use below.

The Veritas Reverse Total 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 and revision total shoulder replacement for the relief of pain and significant disability due to gross rotator cuff deficiency. The system's 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.

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

Note: A CT scan is used to create the Veritas™ patient specific components.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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510(k) Summary

Date Prepared: May 7, 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:

Brianna Prindle
Director of Regulatory Affairs
brianna@restor3d.com

C. Premarket Notification:

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

D. Predicate Devices:

The Veritas Reverse Total Shoulder Arthroplasty System is substantially equivalent to the following devices:

510(k)	Trade Name
Primary Predicate Device	
K243643	restor3d Reverse Total Shoulder Arthroplasty System
Reference Device	
K152754	Comprehensive Vault Reconstruction System (VRS)

E. Indications for Use:

The Veritas Reverse Total 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.

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The Veritas Reverse Total Shoulder System standard components are indicated for primary, fracture and 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 components with porous surface are indicated for uncemented application with the addition of screw fixation.

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

Note: A CT scan is used to create the Veritas™ patient specific components.

F. Device Description:

The Veritas Reverse Total Shoulder Arthroplasty System is intended for patients requiring a reverse shoulder replacement for patients with a functional deltoid muscle and with a deficient rotator cuff. The Veritas Reverse Total Shoulder Arthroplasty System consists of the patient-specific glenoid baseplate, glenosphere intraoperatively affixed to the baseplate, humeral stem, and polymer bearing component affixed to the humeral stem. Additionally, the system includes supporting instrumentation, both patient-specific and standard instrument trays and all required accessories (e.g., security screws, peripheral screws). The proposed device is a robust patient-specific offering for a reverse total shoulder including baseplate offerings with patient specific backside geometry and central fixation location.

The Veritas Reverse Total Shoulder Arthroplasty System includes an AI-based algorithm for auto segmentation of the CT scans within the patient-specific software workflow. The auto segmentation is intended to be used with human intervention for manual cleanup and review. Similar to the indications for use of the Veritas Reverse Total Shoulder Arthroplasty, auto segmentation has only been validated for use in primary shoulder arthroplasty. Ground truth was established through manual segmentation of the CT Scans. The testing data was independent from the training and tuning data, and testing data was from independent clinical sites. CT Scans were collected following the proposed CT Scan protocol for the Veritas Reverse Total Shoulder System. The data set information is provided in the table below.

The algorithm met predefined DICE score-based acceptance criteria of ≥ 0.87 compared to ground truth manual segmentation and was consistent across Scapula (95% CI: 0.88), and Humerus (95% CI: 0.90). The algorithm also met predefined Mean Hausdorff Distance (MHD) based acceptance criteria of ≤3.0 and the result was consistent across Scapula (95% CI: 0.98), and Humerus (95% CI: 0.68)

G. Substantial Equivalence Comparison:

Substantial equivalence of the subject Veritas Reverse Shoulder System to the primary predicate restor3d rTSA (K243643) is based on the following:

- The subject Veritas Reverse Shoulder System has indications for use that are a subset of the indications for use of the predicate restor3d rTSA, with the same intended use and meeting the same acceptance criteria for performance testing.
- The subject Veritas Reverse Shoulder System and reference device VRS (cleared via K152754) share similar technological characteristics, with patient-specific design from CT imaging.

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- The subject Veritas Reverse Shoulder System has the same technological characteristics as the primary predicate restor3d rTSA (K243643) as both devices are additively manufactured from the same material and have an integrally built 3D-printed porous surface.

H. Comparison of Performance:

The subject restor3d Reverse Total Shoulder Arthroplasty System was subject to the following non-clinical performance tests to support the assertion of substantial equivalence:

- Glenoid Baseplate Loosening per ASTM F2028
- Torsional Taper Resistance
- Glenoid Baseplate Fatigue
- Range of Motion Analysis per ASTM F1378
- Impingement analysis
- Cadaver Validation

I. Conclusions:

Based on the comparison of indications for use, intended use, and performance characteristics, as well as the performance testing conducted, the subject Veritas Reverse Total Shoulder System is shown to be substantially equivalent to the primary predicate restor3d rTSA, cleared via K243643.