



May 19, 2025

restor3d
Brianna Prindle
Director of Regulatory Affairs
4001 NC-54 Hwy
Suite 2160
Durham, North Carolina 27709

Re: K243643

Trade/Device Name: restor3d Reverse Total Shoulder Arthroplasty System
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PHX, KWS
Dated: April 18, 2025
Received: April 18, 2025

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 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: 2025.05.19 16:43:03
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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

510(k) Number (if known)

K243643

Device Name

restor3d reverse Total Shoulder Arthroplasty System

Indications for Use (Describe)

The restor3d rTSA 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.

Glenoid component with porous surface is indicated for uncemented biological fixation application only. The restor3d rTSA System glenoid baseplate components are intended for cementless application with the addition of screw fixation.

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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K243643

510(k) Summary

Date Prepared: May 19, 2024

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:	restor3d Reverse Total Shoulder Arthroplasty System
Classification Name:	Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulation Number:	888.3660
Product Code:	PHX, KWS
Classification:	II
Review Panel:	Orthopedic

D. Indications for Use:

The restor3d rTSA 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.

Glenoid component with porous surface is indicated for uncemented biological fixation application only. The restor3d rTSA System glenoid baseplate components are intended for cementless application with the addition of screw fixation.

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

E. Predicate Devices:

The restor3d Reverse Total Shoulder Arthroplasty System is substantially equivalent to the following devices:

510(k)	Trade Name	Manufacturer
Primary Predicate Device		
K193373	Comprehensive® Reverse Shoulder	Zimmer Biomet
Reference Device		
K240591 K192778	Kinos Axiom Total Ankle System	restor3d

F. Device Description:

The restor3d 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 restor3d Reverse Total Shoulder Arthroplasty System consists of the glenoid baseplate, glenosphere intraoperatively affixed to the baseplate, humeral stem, and polymer bearing component affixed to the humeral stem. Additionally, the system includes supporting standard instrument trays and all required accessories (e.g., security screws, peripheral screws).

G. Comparison of Technological Characteristics

The restor3d Reverse Total Shoulder Arthroplasty System is substantially equivalent to the predicate device (Biomet, Comprehensive Reverse Shoulder, K193373) in intended use, indications for use and performance specifications. Additionally, the restor3d Reverse Total Shoulder Arthroplasty System utilizes similar materials and manufacturing processes as the reference device, the Kinos Axiom Total Ankle System (K240591). The subject and predicate device is comparable in terms of design characteristics; however, the subject rTSA system differs from the predicate in the manufacturing process, as the glenoid baseplate and humeral stems are additively manufactured with a porous surface.

H. Summary of Non-Clinical Testing

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
- Glenoid Baseplate Fatigue and corrosion analysis
- Morse Taper Disassembly Strength per ASTM F2009
- Humeral Stem Fatigue and corrosion analysis
- Bone Screw Testing per ASTM F543
- Poly Liner Performance Tests per ASTM F1820
- Range of Motion Analysis per ASTM F1378
- Wear Analysis



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I. Conclusions:

In summary, the non-clinical bench testing demonstrates that the subject restor3d rTSA system is substantially equivalent to the predicate Zimmer Biomet Comprehensive Reverse Shoulder (K193373). The subject rTSA system does not raise any different questions of safety or effectiveness as compared to the predicate Zimmer Biomet Comprehensive Reverse Shoulder (K193373).