December 5, 2025

restor3d, inc.
Knox Pittman
Regulatory Engineer
4001 NC-54 Hwy
Suite 3160
Durham, North Carolina 27709

Re: K252067
Trade/Device Name: Velora Acetabular System
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip Joint Metal/Polymer/Metal Semi-Constrained Porous-Coated Uncemented Prosthesis
Regulatory Class: Class II
Product Code: LPH, LZO, MEH, OQG
Dated: November 7, 2025
Received: November 7, 2025

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 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,

RYAN TROMBETTA -S

For: Limin Sun, Ph.D.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K252067

Device Name
Velora Acetabular System

Indications for Use *(Describe)*
The Velora Acetabular System is indicated for use in skeletally mature individuals undergoing total hip replacement due to:

• A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, avascular necrosis, or congenital hip dysplasia.
• Treatment of non-displaced non-unions of the hip, femoral neck fractures, and trochanteric fractures of the proximal femur with head involvement, unmanageable by other techniques.
• Revision procedures for failed previous hip surgery (excluding situations where hardware is present).

The implants in the Velora Acetabular System are intended for cementless fixation using an anterior or posterior surgical approach.

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.

restor3d

Date Prepared: December 5, 2025

510(k) Summary

In accordance with the requirements of 21 CFR 807.92, this information serves as a Summary of Safety and Effectiveness for the use of the restor3d Velora Acetabular System.

A. 510(k) Sponsor:

restor3d, inc.
4001 NC 54 Highway, Suite 3160
Durham, North Carolina, 27709

B. Primary Correspondent

Knox Pittman
Regulatory Engineer
(404) 317-2436 (direct)
knox.pittman@restor3d.com

C. Premarket Notification

Trade Name:	Velora Acetabular System
Common Name:	Total Hip Replacement
Classification Name:	Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulation Number:	21 CFR 888.3358
Product Code:	LPH, LZO, MEH, OQG
Classification:	II
Review Panel:	Orthopedic

D. Predicate Devices:

510(k) Number	Trade Name
Primary Predicate Device	
K190904	BeneFIT Hip System *Now marketed as Cordera Hip System*
Additional Predicate Devices	
K243977	EMPHASYS Acetabular System
K190660	G7 Acetabular System

E. Indications for Use

The Velora Acetabular System is indicated for use in skeletally mature individuals undergoing total hip replacement due to:

- A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, avascular necrosis, or congenital hip dysplasia.

restor3d

Date Prepared: December 5, 2025

- Treatment of non-displaced non-unions of the hip, femoral neck fractures, and trochanteric fractures of the proximal femur with head involvement, unmanageable by other techniques.
- Revision procedures for failed previous hip surgery (excluding situations where hardware is present).

The implants in the Velora Acetabular System are intended for cementless fixation using an anterior or posterior surgical approach

F. Device Description

This submission introduces the Velora Acetabular System, which consists of acetabular cups that are additively manufactured from titanium alloy (Ti-6Al-4V per ASTM F2924) with an integrally built 3D-printed porous structure (TIDAL Technology) and standardized polyethylene (ASTM F2695, ASTM F2565) liners. The liners are available in standard offset, lateral offset, lipped, and face-changing geometries. The cups are provided in sizes 40mm to 72mm, and the mating liners are provided in sizes from Grp A to Grp K, as outlined in the table below. There are additional single-use trial liners and reusable instruments offered with the Velora Acetabular System. The Velora Acetabular System devices are compatible with the previously cleared Conformis Actera (K231178) and Cordera (K192198) femoral implants, acetabular screws, and reusable instruments.

Liner Group	Compatible Cup Size	Liner Inner Diameter(s)
GRP A	40mm	28mm
	42mm	
GRP B	44mm	32mm
	46mm	
GRP C	48mm	36mm
GRP D	50mm	36mm
GRP E	52mm	36mm, 40mm
GRP F	54mm	36mm, 40mm
GRP G	56mm	36mm, 40mm
	58mm	
GRP H	60mm	36mm, 40mm
	62mm	
GRP J	64mm	36mm, 40mm
	66mm	
	68mm	
	70mm	
GRP K	72mm	36mm, 40mm

restor3d

Date Prepared: December 5, 2025

G. Substantial Equivalence Comparison

Substantial equivalence of the subject Velora Acetabular System to the primary predicate cleared via K190904 is based on the following:

- The subject Velora Acetabular System and the primary predicate K190904 have the same indications for use and intended use, and meet the same acceptance criteria for performance testing.
- The subject Velora Acetabular System and reference devices EMPHASYS Acetabular System (K243977) and G7 Acetabular System (K190660) share similar designs and sizes.
- The subject Velora Acetabular System differs in technological characteristics from the primary predicate (K190904) as the device is additively manufactured and has an integrally built 3D-printed porous surface. The differences in technological characteristics were assessed through mechanical testing and do not raise different questions of safety or effectiveness.

H. Non-Clinical Performance Evaluation

- Axial disassembly (ASTM F1820)
- Lever-out disassembly (ASTM F1820)
- Torque-out disassembly (ASTM F1820)
- Liner impingement (ASTM F2582)
- Acetabular Cup Fatigue (ASTM F3090)
- Range of motion (ISO 21535)
- Wear performance rationale
- Acetabular Cup Deformation (ISO 7206-12)

I. Conclusions

Based on the comparison of indications for use, intended use, as well as the performance testing conducted, the subject Velora Acetabular System is shown to be substantially equivalent to the primary predicate cleared via K190904. The differences in technological characteristics between the subject and predicate devices do not raise different questions of safety or effectiveness.