September 3, 2025

restor3d
Knox Pittman
Regulatory Engineer
4001 E. NC 54 Highway
Suite 3160
Durham, North Carolina 27709

Re: K252454
Trade/Device Name: Kinos Total Ankle System
Regulation Number: 21 CFR 888.3110
Regulation Name: Ankle Joint Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: HSN
Dated: August 4, 2025
Received: August 4, 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,

Lixin Liu -S

Lixin Liu, 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)*

K252454

Device Name

Kinos Total Ankle System

Indications for Use *(Describe)*

The Kinos Total Ankle System is indicated for patients with ankle joints damaged by severe rheumatoid, post-traumatic, or degenerative arthritis. The Kinos Total Ankle System is additionally indicated for patients with failed previous ankle surgery. The Kinos Total Ankle System is intended for cement use only.

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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510(k) Summary

Date Prepared: 02 September 2025

In accordance with 21 CFR 807.92 requirements, this information serves as a Summary of Substantial Equivalence for the Kinos Total Ankle System.

A. 510(k) Sponsor:

restor3d, inc.
4001 E. 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:	Kinos Total Ankle System
Common Name:	Total Ankle Replacement
Classification Name:	Ankle joint metal/polymer semi-constrained cemented prosthesis
Regulation Number:	21 CFR 888.3110
Product Code:	HSN
Classification:	II
Review Panel:	Orthopedic

D. Indications for Use:

The Kinos Total Ankle System is indicated for patients with ankle joints damaged by severe rheumatoid, post-traumatic, or degenerative arthritis. The Kinos Total Ankle System is additionally indicated for patients with failed previous ankle surgery. The Kinos Total Ankle System is intended for cement use only.

E. Predicate Devices:

The addition of intermediate sizes and sterilization method to the Kinos Total Ankle System is substantially equivalent to the following devices:

510(k)	Trade Name	Manufacturer
Predicate Device		
K242868	Kinos Total Ankle System	restor3d, inc.
Reference Devices		
K232595	Kinos Axiom Total Ankle System	restor3d, inc.
K242356	TIDAL Fusion Cage System	restor3d, inc.

F. Device Description:

The subject Kinos Total Ankle System consists of implant and instrument components designed to preserve motion in patients with ankle arthritis or previously failed ankle surgery. The device is a fixed bearing and semi-constrained implant construct, intended for replacement of the articulating surfaces of the ankle that have been affected by a disease state or injury. The subject device provides limited mobility to a patient by restoring alignment of the articulating surfaces, reducing pain, and providing flexion-extension movement within the ankle joint. The tibial and talar implants are intended to be used with bone cement. The subject Kinos Total Ankle System consists of three implant components – a tibial implant affixed to the tibia, a bearing implant assembled to the tibial implant and a talar implant affixed to the talus. The tibial implant and bearing implant, assembled intraoperatively, function together and articulate with the talar implant to create a fixed bearing prosthesis, replacing the articulating surface of the tibiotalar joint. The subject line extension includes additional intermediate sizes for the tibial implants. Additionally, the line extension introduces steam (moist heat) sterilization for the tibial implants for sterilization on-site at the hospital.

The Kinos Total Ankle Tibial Implants subject of this 510(k), are compatible with:

- All Kinos Axiom Total Ankle System Talar and Bearing Components and associated instrumentation cleared via K192778
- All Kinos Axiom Total Ankle System r3 Talar and Vitamin E Bearing Components and associated instrumentation cleared via K240591

G. Substantial Equivalence Comparison:

Substantial equivalence of the line extension Tibial Implant to the predicate Kinos Total Ankle Tibial Implants are based on the following:

- The subject Tibial Implant and predicate Kinos Total Ankle Tibial Implant share identical intended use, indications for use, performance characteristics, and design.
- The subject Tibial Implant and predicate Kinos Total Ankle Tibial Implant have identical technological characteristics including additive manufacturing, TIDAL integrally built porous surface and modular stem fixation (K242868). The subject Tibial Implant can also have X-Stem fixation which is identical to the reference device Kinos Axiom Total Ankle (K232595).
- While the subject Tibial Implant and predicate Kinos Total Ankle System have different sterilization methods, they are sterilized to the same sterility assurance level (SAL) of $1x10^{-6}$, and the subject and reference device TIDAL Fusion Cage System share identical packaging, sterilization methods, and SAL.
- While the subject Tibial Implant contains additional sizes as compared to the predicate Kinos Total Ankle System, these sizes are bounded by the same minimum and maximum sizes and do not introduce any new technological characteristics.

H. Performance Testing:

No performance testing was performed to establish substantial equivalence to the subject device to the predicates for the additional sizes. The subject Kinos Total Ankle System has identical performance characteristics to the predicate device cleared via K242868. The additional, intermediate sizing options have been assessed via engineering analysis and have been shown to not present a new worst case as compared to the predicate cleared via K242868.

The subject Kinos Total Ankle System were adopted into the previous sterilization validation which is identical to the TIDAL Fusion Cage (K242356). The steam sterilization process is validated to SAL $1x10^{-6}$ according to ISO 17665:2024. The subject Kinos Total Ankle System does not present a new worst case as compared to the reference device cleared via K242356.

I. Conclusion:

Based on the comparison of the intended use, indications for use, and technological characteristics, the subject Kinos Total Ankle System is substantially equivalent to the predicate Kinos Total Ankle System. Neither the addition of steam sterilization, nor the additional intermediate sizing options of the Tibial Implant component raises any different questions of safety or effectiveness.