October 18, 2024

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

Re: K242868
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: September 20, 2024
Received: September 20, 2024

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, 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242868

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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510(k) Summary

Date Prepared: Sept 20th, 2024

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 also indicated for patients with failed previous ankle surgery. The Kinos Total Ankle System is intended for cement use only.

E. Predicate Devices:

The expansion of indications to the Kinos Total Ankle System is substantially equivalent to the following devices:

510(k)	Trade Name	Manufacturer
Primary Predicate Device		
K241482	Kinos Total Ankle System	restor3d, Inc.
Reference Device		
K232595	Kinos Axiom Total Ankle System	restor3d, inc.

F. Device Description:

The subject Kinos Total Ankle System is identical to the predicate device cleared under K241482. The purpose of this submission is to update the indications for use for the subject device to include primary ankle arthroplasty (i.e., ankle joints damaged by severe rheumatoid, post-traumatic, or degenerative arthritis).

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 tibial segments which are assembled intraoperatively to the tibial base plate to enhance tibial fixation height in the tibia.

The additively manufactured r3 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. Performance Testing:

No performance testing was performed to establish substantial equivalence of the subject device to the predicates. The subject Kinos Total Ankle System components are identical to the predicate device cleared via K241482. However, a dimensional analysis comparison of device components and a surgical technique comparison was made to the X-Stem Tibial Implant of the Kinos Total Ankle System, K232595, that is also indicated for primary and revision procedures. This comparison demonstrated the risk of bone loss due to the surgical resection of the tibia and implantation of components was the same between the two device designs, supporting the indication extension for the subject device.

H. Substantial Equivalence Comparison:

Substantial equivalence of the r3 Tibial Implant to the predicate r3 and X- Stem Tibial Implant is based on the following

- The subject r3 Tibial Implant and r3 Tibial Implant share identical performance characteristics, design, and sizes.
- The subject Tibial Implant and reference device X-Stem Tibial Implant have the same indications for use and the same intended use
- The subject Tibial Implant and reference device X-Stem Tibial Implant share similar performance characteristics, design, and sizes

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. The addition of indication for primary ankle arthroplasty does not raise any different questions of safety or effectiveness.