November 28, 2023

restor3d
Brianna Prindle
Head of Regulatory
4001 E. NC 54 Highway
Suite 3160
Durham, North Carolina 27709

Re: K232595
Trade/Device Name: Kinos Axiom 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 13, 2023
Received: September 13, 2023

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.

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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K232595

Device Name

Kinos Axiom Total Ankle System

Indications for Use *(Describe)*

The Kinos Axiom Total Ankle System is indicated for patients with ankle joints damaged by severe rheumatoid, posttraumatic, or degenerative arthritis. The Kinos Total Ankle System is additionally indicated for patients with failed previous ankle surgery. The Kinos Axiom 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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

restor3d

510(k) Summary

Date Prepared: November 26th, 2023

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 Kinos Axiom Total Ankle System.

A. 510(k) Sponsor:

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

B. Primary Correspondent:

Brianna Prindle
Head of Regulatory
(786) 521-0501 (direct)
brianna@restor3d.com

C. Premarket Notification:

Trade Name:	Kinos Axiom 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 Axiom 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 Axiom Total Ankle System is intended for cement use only.

E. Predicate Devices:

The Kinos Axiom Total Ankle System is substantially equivalent to the following devices:

510(k)	Trade Name	Manufacturer
Primary Predicate Device		
K192778	Kinos Axiom Total Ankle System	Restor3d, Inc. *Cleared under Kinos Medical*
Secondary Predicate Device		
K140749	Infinity Total Ankle System	Wright Medical
Reference Device		
K220523	restor3d TiDAL Lumbar Interbody Fusion Device	restor3d, Inc.
K210390	Apex 3D Total Ankle Replacement System	Paragon 28, Inc.

F. Device Description:

The subject Kinos Axiom Total Ankle System is an implant and instrument system 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 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 device is intended to be used with bone cement. The subject Kinos Axiom 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 tibial-talar joint. The subject line extension tibial implant is additively manufactured from Ti-6Al-4V (ASTM F2924) and features a modified stem for fixation into the tibia.

G. Performance Testing:

The modified device was subjected to the following performance testing and/or analyses to establish substantial equivalence in comparison to the predicate device.

- Strength Testing per ASTM F2665
- Bone Stability Testing
- Porous Surface Characterization
- Biocompatibility per ISO 10993-1:2018

H. Substantial Equivalence Comparison:

Substantial equivalence of the line extension tibial implant to the predicate device is based on the following:

- The line extension tibial implant and predicate device have the same indications for use and the same intended use.
- The line extension tibial implant and predicate device share similar

performance characteristics, design, and sizes (dimensions are comparable to those offered by predicate systems).

- Changes in technological characteristics, including material and manufacturing methods, are not shown to raise any different questions of safety or effectiveness.

I. Conclusion:

Based on comparison of the intended use, indications for use and technological characteristics, the subject Kinos Axiom Total System is substantially equivalent to the predicate Kinos Axiom Total Ankle System. The change in material specification to ASTM F2924 for the addition of additive manufacturing, minor changes in dimensions and sizes and changes in technological characteristics do not raise any different questions of safety or effectiveness.