June 30, 2020

Kinos Medical
℅ Alyssa Schwartz
Regulatory Consultant
Alyssa Schwartz
992 Old Eagle School Road Suite 907
Wayne, Pennsylvania 19087

Re: K192778
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: May 22, 2020
Received: May 26, 2020

Dear Alyssa Schwartz:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Ting Song, Ph.D., R.A.C.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192778

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, 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.

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.

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510(k) SUMMARY

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807.92, this information serves as a Summary of Safety and Effectiveness for the use of the Kinos Axiom Total Ankle System.

1. Submitted By:

Brian Garvey
CEO
Kinos Medical
992 Old Eagle School Rd, Suite 907
Wayne, PA 19087

Date: June 30, 2020

Contact Person:

Alyssa Schwartz, MS, RAC
Regulatory Affairs Consultant
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Email: aschwartzconsulting@gmail.com

2. Proprietary Name: Kinos Axiom Total Ankle System

Common Name: Ankle Prosthesis

Classification Name and Reference: 21 CFR 888.3110, Class II

Device Product Code and Device Panel: HSN: Orthopedic

3. Predicate Device: K123954 and K140749
Wright Medical
Infinity Total Ankle System

4. Device Description

The subject Kinos Axiom Total Ankle System is an implant and instrument system designed to preserve motion in patients with ankle arthritis. 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 comprises three implant components – a tibial implant affixed to the tibia, a bearing implant assembled to the tibial implant and 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.

5. Intended Use

Intended Use:

The Kinos Axiom Total Ankle System is intended to provide a patient with limited mobility by restoring alignment, reducing pain and replacing the flexion/extension movement of the ankle joint.

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.

6. Technological Characteristics Comparison

The general technological features of the Kinos Axiom Total Ankle System are similar to the predicate devices with regard to design and materials.

7. Substantial Equivalence – Non-Clinical Evidence

The following non-clinical analysis was performed:

- Fatigue, Constraint, Contact Area, Strength Testing and Wear Performance and Range of Motion Analyses per ASTM F2665
- Biocompatibility per ISO 10993-1: 2018
- Pyrogenicity per ANSI/AAMI/ST72: 2011

The results of this analysis show that the subject Kinos Axiom Total Ankle System can be expected to perform at least as well as the legally marketed predicates referenced above. The safety and effectiveness of the Kinos Axiom Total Ankle System is adequately supported by the substantial equivalence information, materials information, and comparison of design characteristics provided within this 510(k) submission.

8. Substantial Equivalence – Clinical Evidence

n/a – no clinical evidence was required to determine substantial equivalence

9. Substantial Equivalence – Conclusions

The design characteristics of the subject system do not raise any new types of questions of safety or effectiveness. From the evidence submitted in this 510(k), the subject devices can be expected to perform at least as well as the predicate systems.