March 30, 2023

restor3d, inc.
Brianna Prindle
Head of Regulatory
311 W. Corporation St.
Durham, North Carolina 27701

Re: K223326
Trade/Device Name: Axiom PSR System
Regulation Number: 21 CFR 888.3110
Regulation Name: Ankle Joint Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: OYK
Dated: February 24, 2023
Received: February 24, 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 (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,

Limin Sun -S

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)*
K223326

Device Name
Axiom PSR System

Indications for Use *(Describe)*
The Axiom PSR System is intended to be used as patient specific surgical planning and instrumentation to assist in the positioning of total ankle replacement components intraoperatively, and in guiding bone cutting. The Axiom PSR System is intended for use with the Kinos Axiom Total Ankle System and its cleared indications for use.

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

510(k) Number: K223326

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92.

A. 510(k) Owner:

restor3d, inc.
311 W. Corporation St.
Durham, NC 27701

B. Primary Correspondent:

Brianna Prindle
Head of Regulatory
brianna@restor3d.com

C. Premarket Notification:

Submission Type:	Traditional 510(k)
Trade Name:	Axiom PSR System
Classification:	Class II
Product Code:	OYK
Classification Name:	Ankle Arthroplasty Implantation System
Regulation Number:	21 CFR 888.3110
Regulation Name:	Ankle joint metal/polymer semi-constrained cemented prosthesis

D. Indications for Use:

The Axiom PSR System is intended to be used as patient specific surgical planning and instrumentation to assist in the positioning of total ankle replacement components intraoperatively, and in guiding bone cutting. The Axiom PSR System is intended for use with the Kinos Axiom Total Ankle System and its cleared indications for use.

E. Predicate Devices:

Kinos Axiom PSR is substantially equivalent to the following devices:

510(k)	Trade Name	Manufacturer
Primary Predicate Device		
K193432	Vantage PSI System	Medical Modeling – A 3D Systems Company
Secondary Predicate Devices		

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510(k)	Trade Name	Manufacturer
K192778	Kinos Axiom Total Ankle System	restor3d
K220523	Tidal Lumbar Interbody Fusion Device	restor3d

F. Device Description:

restor3d's Axiom PSR System is an ankle surgical guide system, designed for an individual patient from the patient's CT imaging scans. The subject Axiom PSR System is intended to aid in the placement of Kinos Axiom Total Ankle System (K192778) implant components when used in conjunction with the Kinos Axiom standard, reusable instruments. The Axiom PSR System includes preoperative plans developed with and approved by the operative surgeon, tibia and talus resection guides, manufactured from implant grade titanium, bone models manufactured from biocompatible polymer for use with the Kinos Axiom Total Ankle System.

G. Comparison of Technological Characteristics

The intended use and technological characteristics of the subject Axiom PSR System are either identical or substantially equivalent to the predicate device (Vantage PSI System, K193432).

The principles of operation and technological characteristics are substantially equivalent between the Axiom PSR System and the identified predicate. Specifically, the predicate device includes pre-operative planning from patient CT imaging scans, 3D printing of patient specific bone models and resection guides. Both the subject and predicate system perform bone resection cuts directly through the patient specific guides and are used to aid in the placement of a previously cleared total ankle system when used in conjunction with standard instruments of their respective total ankle system.

The subject Axiom PSR System uses the same fundamental technologies employed in the digital workflow as the predicate device, including medical image transformation and manipulation in a CAD environment with digital outputs subsequently used for 3D printing of the patient specific devices.

The subject Axiom PSR System resection guides and bone models are made from implant grade titanium alloy (Ti-6Al-4V) and biocompatible polymer. Whereas the predicate device resection guides are made from polyamide. The biocompatibility of the subject Axiom PSR System resection guides and bone models has been assessed through testing in support of this and other 510(k) submissions and does not represent any new or increased risks with respect to technological characteristics.

H. Summary of Performance Testing

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Non-clinical, cadaver testing was conducted to validate the digital design workflow and assess the accuracy of the subject Axiom PSR System, compared to the previously cleared Kinos Axiom Total Ankle System. Post-operative CT scans were obtained, and the final implant positions were evaluated in 3D space about six degrees of freedom and then compared to the pre-operative plans. Cadaver validation testing demonstrated that the subject Axiom PSR System was at least as accurate or more accurate than using the previously cleared Kinos Axiom Total Ankle System standard instruments alone, with respect to implant placement relative to the preoperative plan in six degrees of freedom.

Process qualification was performed to demonstrate manufactured devices meet the output specifications of the digital design workflow.

Cleaning, biocompatibility, sterilization, and shelf life were evaluated against previously conducted validations. The evaluations demonstrate acceptable adoption into previously established manufacturing processes, materials and specifications employed in restor3d's previously cleared implant and instrument systems, including the restor3d Tidal Lumbar Interbody Fusion Device (K220523), therefore the subject device does not represent any new or increased concerns of safety or efficacy.

I. Conclusions:

Based on comparison of the intended use, indications for use and technological characteristics, the subject Axiom PSR System is substantially equivalent to the predicate Vantage PSI System. Minor differences in the material and technological considerations do not raise any new or different questions of safety or effectiveness. Additionally, the cadaveric testing demonstrates the system performs in accordance with its intended use and is as safe, effective and performs as well as the previously cleared Kinos Axiom Total Ankle System (K192778) predicate device.