August 30, 2024

3D Systems, Inc.
Ashley Dawson
Director, Regulatory Affairs
5381 South Alkire Circle
Littleton, Colorado 80127

Re: K241326
Trade/Device Name: Cadence Ankle PSI 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: July 31, 2024
Received: July 31, 2024

Dear Ashley Dawson:

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)*

K241326

Device Name

Cadence Ankle PSI System

Indications for Use *(Describe)*

The Cadence Ankle PSI 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 Cadence Ankle PSI System is intended for use with Smith + Nephew's Cadence 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

1. INTRODUCTION

This document contains the 510(k) summary for the Cadence Ankle PSI System. The content of this summary is based on the requirements of 21 CFR 807.92.

2. SUBMITTER

Name: 3D Systems, Inc.

Address: 5381 South Alkire Circle
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Phone: (720) 643-1001
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Official Contact: Dr. Ashley Dawson
Director of Regulatory Affairs

Date Prepared: August 30, 2024

3. DEVICE

Trade Name: Cadence Ankle PSI System

Common Name: Ankle Arthroplasty Implantation System

Classification Name: Ankle joint metal/polymer semi-constrained cemented prosthesis

Classification: Class II, 21 CFR 888.3110

Product Code: OYK

4. PREDICATE DEVICE

Predicate Device: K193432 Vantage® PSI System, Product Code OYK

5. REFERENCE DEVICE

Reference Device: K151459 Cadence Total Ankle Replacement System, Produce Code HSN

6. DESCRIPTION OF THE DEVICE

3D Systems' Cadence Ankle PSI System consists of patient specific outputs including surgical guides, anatomical models, and case reports. The Cadence Ankle PSI System guides are made from biocompatible nylon and surgical grade stainless steel and are designed to fit the contours of the patient's distal tibial and proximal talar anatomy. The surgical guides in combination with the Smith+Nephew Cadence Total Ankle System instruments, facilitate the positioning of Cadence Total Ankle Prostheses.

7. INTENDED USE/INDICATIONS FOR USE

The Cadence Ankle PSI 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 Cadence Ankle PSI System is intended for use with Smith + Nephew's Cadence Total Ankle System and its cleared indications for use.

8. INDICATIONS FOR USE COMPARISON

The Cadence Ankle PSI System has the same Indications for Use as the predicate device with the only change being the orthopedic implant that the Patient-Specific Instrumentation is guiding.

9. TECHNOLOGICAL COMPARISON

The principles of operation and technological characteristics are substantially equivalent between the subject Cadence Ankle PSI System and the predicate Vantage PSI System (K193432). Both the predicate and the subject devices are designed with CT-based methods to produce patient-specific instrumentation. Cadence Ankle PSI System guides are manufactured using SLS technology with DuraForm® ProX PA (polyamide) material and surgical stainless steel components. Both the subject and predicate devices guide the placement of pins and resections of tibial and talar anatomies for total ankle arthroplasties. The difference between the subject device and the predicate device is that the subject device is designed to guide the accurate placement of the Smith+Nephew Cadence Total Ankle Prosthesis.

10. NON-CLINICAL AND/OR CLINICAL TESTS SUMMARY

Non-clinical performance testing on the Cadence Ankle PSI System included Mechanical Integrity (post-processing), Debris Generation, and Intra- and Inter-Designer Variability analysis. The Cadence Ankle PSI System met all acceptance criteria for all performance tests.

Non-clinical cadaveric comparison testing was performed to compare Implant Alignment Accuracy and Guide Usability between the subject device and reference device. Accuracy and functionality were shown to be similar to that of the standard instrumentation currently used for the Cadence Total Ankle System.

11. CONCLUSION

Based on a comparison of the intended use, indications for use, and technological characteristics, the Cadence Ankle PSI System is substantially equivalent to the identified predicate device. Additionally, the non-clinical testing supports that the system performs in accordance with its intended use and is as safe, as effective, and performs as well as the predicate device.