August 29, 2023

NuVasive Specialized Orthopedics, Inc.
Miriam Cervantes
Senior Regulatory Affairs Specialist
101 Enterprise, Suite 100
Aliso Viejo, California 92656

Re: K230765
Trade/Device Name: Precice Ankle Salvage System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB, HWC
Dated: July 28, 2023
Received: July 31, 2023

Dear Miriam Cervantes:

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,

Farzana Sharmin -S

Digitally signed by Farzana Sharmin -S
Date: 2023.08.29 17:48:49 -04'00'

Farzana Sharmin, 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)*
K230765

Device Name
Precice Ankle Salvage System

Indications for Use *(Describe)*

The Precice Ankle Salvage System is indicated for tibio-talo-calcaneal fusions in adults. When used for tibio-talo-calcaneal fusion, the Precice Ankle Salvage System may be used for open and closed fracture fixation, pseudarthrosis, mal-unions, non-unions, or bone transport of long bones adjacent to the fusion site. The device may be used for subsequent limb lengthening once tibio-talo-calcaneal fusion has been achieved.

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.

Precice Ankle Salvage System
510(k) Summary

In accordance with Title 21 of the Code of Federal Regulations, Part 807, and in particular 21 CFR §807.92, the following summary of information is provided:

A. Submitted by:

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mcervantes@nuvasive.com
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NuVasive Specialized Orthopedics, Inc.
101 Enterprise, Suite 100
Aliso Viejo, CA 92656
Telephone: (909) 229-7836

Date Prepared: August 23, 2023

B. Device Name

Trade or Proprietary Name:	Precice Ankle Salvage System
Common or Usual Name:	Rod, Fixation, Intramedullary and Accessories
Classification Name:	Intramedullary Fixation Rod
Device Class:	Class II
Classification:	21 CFR § 888.3020
Product Code:	HSB
Common or Usual Name:	Screw, Fixation, Bone
Classification Name:	Smooth or threaded metallic bone fixation fastener
Device Class:	Class II
Classification:	21 CFR § 888.3040
Product Code:	HWC

C. Predicate Devices

The subject Precice Ankle Salvage System is substantially equivalent to the primary predicate device *Precice Ankle Salvage System* (K200430). The *Precice Intramedullary Limb Lengthening System* (K220234) served as an additional predicate.

D. Device Description

The Precice Ankle Salvage System is a tibio-talo-calcaneal fusion system that consists of the Precice Ankle Salvage nail, locking screws, end caps, and associated general instruments. The Precice Ankle Salvage nail is compatible with an accessory External Remote Controller (ERC). The Precice Ankle Salvage nail, endcap, and locking screws are supplied sterile by gamma radiation. The Precice Ankle Salvage nail contains an enclosed rare earth magnet, telescoping distraction rod, and planetary gearing which allows the length of the nail to be adjusted non-

invasively by the ERC. Retraction of the Precice Ankle Salvage nail can be utilized to maintain compression across the tibio-talo-calcaneal joints post-operatively. The Precice Ankle Salvage nail can also be used to subsequentially correct a limb length discrepancy that may result after the tibio-talo-calcaneal fusion procedure.

The purpose of this submission is to implement material and design changes to the predicate *Precice Ankle Salvage System* (K200430) to create a product line extension which includes the Precice Ankle Salvage nail, end caps, and locking screws in titanium. The subject device is manufactured from medical grade Titanium alloy (Ti-6Al-4V) per ASTM F136. The Precice Ankle Salvage nail is available in various nail styles, diameters, and lengths to accommodate a variety of patient anatomies and surgeon preference. The locking screws are available in a variety of diameters, lengths, and thread styles. The ERC is available in several compatible models. These modifications do not change the indications for use or intended use of the device, nor do they change the fundamental scientific technology of the device.

E. Indications for Use

The Precice Ankle Salvage System is indicated for tibio-talo-calcaneal fusions in adults. When used for tibio-talo-calcaneal fusion, the Precice Ankle Salvage System may be used for open and closed fracture fixation, pseudarthrosis, mal-unions, non-unions, or bone transport of long bones adjacent to the fusion site. The device may be used for subsequent limb lengthening once tibio-talo-calcaneal fusion has been achieved.

F. Comparison of Indications for use with the Predicate Device

The Precice Ankle Salvage System has the same intended use as the predicate device *Precice Ankle Salvage System* (K200430). Both the subject and predicate device achieve tibio-talo-calcaneal fusion by providing sustained compression across the fusion site post-operatively. The subject device indications for use differ from the predicate device *Precice Ankle Salvage System* (K200430) indications by specifying that it is for adults. This difference in indications does not change the intended use or fundamental scientific technology of the device so it does not affect the intended surgical use or the safety and effectiveness of the device.

Additionally, the Precice Ankle Salvage System has the same intended use as both the predicate *Precice Ankle Salvage System* (K200430) and *Precice Intramedullary Limb Lengthening System* (K220234) for fracture fixation and limb lengthening.

Therefore, the subject device does not create a new intended use.

G. Comparison of Technological Characteristics with the Predicate Device

As was established in this submission, the subject Precice Ankle Salvage System is substantially equivalent to the primary predicate *Precice Ankle Salvage System* (K200430), which was previously cleared by the FDA for commercial distribution in the United States. The subject device has been shown to be substantially equivalent and have equivalent technological characteristics to the predicates through comparison in areas including design, principles of operation, labeling/intended use, material composition, and function.

The following table describes the summary comparison of technological characteristics of the subject device with the predicate devices.

Predicate	***Subject Device***	***Precice Ankle Salvage System (K200430)***	***Precice Intramedullary Limb Lengthening System (K220234)***
Indications for Use	The Precice Ankle Salvage System is indicated for tibio-talo-calcaneal fusions in adults. When used for tibio-talo-calcaneal fusion, the Precice Ankle Salvage System may be used for open and closed fracture fixation, pseudarthrosis, mal-unions, non-unions, or bone transport of long bones adjacent to the fusion site. The device may be used for subsequent limb lengthening once tibio-talo-calcaneal fusion has been achieved.	The Precice Ankle Salvage System is intended for tibio-talo-calcaneal fusions. When used TTC fusion, the Precice Ankle Salvage System may be used for open and closed fracture fixation, pseudarthrosis, mal-unions, non-unions, or bone transport of long bones adjacent to the fusion site. The device may be used for subsequent limb lengthening once tibio-talo-calcaneal fusion has been achieved.	The Precice Intramedullary Limb Lengthening System is indicated for limb lengthening, open and closed fracture fixation, pseudarthrosis, malunions, nonunions, or bone transport of long bones in patients age 18 years and older and indicated for limb lengthening of the femur and tibia in pediatric patients (greater than 12 years old).
Summary of the subject device technology <u>similarities</u> compared to the predicate device	Principle of Operation: sustained compression across the fusion site & distraction osteogenesis Geometry: similar implant design and identical diameters and lengths for the nail Material Composition: Titanium alloy (Ti-6Al-4V) Similar screw diameters and styles	Principle of Operation: sustained compression across the fusion site & distraction osteogenesis Geometry: similar implant design and identical diameters and lengths for the nail Similar screw diameters and styles	Principle of Operation: distraction osteogenesis Material Composition: Titanium alloy (Ti-6Al-4V) Similar screw diameters and styles
Summary of the subject device technology <u>differences</u> compared to the predicate device	Similar to K200430 but offered in the same material as K220234	Device offers screw diameters in longer lengths than the subject device	Device nail is not offered with a threaded distal end like the subject device Device nail offers a longer total stroke length for limb lengthening than the subject device Device screws not offered in a larger screw diameter like the subject device

H. Performance Data

Nonclinical performance verification testing was performed to demonstrate that the subject Precice Ankle Salvage System is substantially equivalent to the predicate devices.

The following testing was performed:

Testing Description	Applicable Standard
Dynamic Compression Bending Strength	ASTM F1264 - *Standard Specification and Test Methods for Intramedullary Fixation Devices*
Static Compression Bending Strength	
Torsion	
Tensile Strength	
Axial Pullout Strength	ASTM F543 - *Standard Specification and Test Methods for Metallic Medical Bone Screws*
Insertion Torque	
Ultimate Torque	
Distraction and Retraction Force	N/A
Wear Debris Testing	N/A
Corrosion Assessment	N/A

The results demonstrate that the subject Precice Ankle Salvage System is substantially equivalent to the primary predicate.

I. Conclusions

The subject device, the Precice Ankle Salvage System, has been shown to be substantially equivalent to the legally marketed primary predicate device for its intended use.