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

September 16, 2020

Re: K200430
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: August 17, 2020
Received: August 19, 2020

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,

For Michael Owens
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)*
K200430

Device Name
Precice® Ankle Salvage System

Indications for Use *(Describe)*
The Precice Ankle Salvage System is intended for tibio-talo-calcaneal fusions. When used for 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.

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.

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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:

Miriam Cervantes
Regulatory Affairs Specialist
NuVasive Specialized Orthopedics, Inc.
101 Enterprise, Suite 100
Aliso Viejo, CA 92656
Telephone: (909) 229-7836

Date Prepared: September 15, 2020

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 and 888.3040
Product Code:	HSB, HWC

C. Predicate Devices

The subject *Precice Ankle Salvage System* is substantially equivalent to the following predicate devices:

For tibio-talo-calcaneal fusion the *Precice Ankle Salvage System* is substantially equivalent to the predicate device *DynaNail TTC Fusion System* (K171376).

For fracture fixation, including opened and closed fracture fixation, pseudarthrosis, mal-unions, non-unions, or bone transport of long bones adjacent to the fusion site, and for subsequent limb lengthening the *Precice Ankle Salvage System* is substantially equivalent to the predicate device *Precice Stryde System* (K180503).

In addition, the following reference device was used to establish substantial equivalence, *Precice System* (K173129).

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 external remote controller (ERC). The Precice Ankle Salvage Nail and endcap are supplied sterile by gamma radiation. The locking screws are offered either sterile or non-sterile.

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 correct a limb length discrepancy that may result after the TTC fusion procedure.

The subject device is manufactured from medical grade Biodur 108 alloy per ASTM F2229. 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.

E. Indications for Use

The *Precice Ankle Salvage System* is intended for tibio-talo-calcaneal fusions. When used for 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.

F. Comparison of Indications for use with the Predicate Device

The *Precice Ankle Salvage System* has the same intended use as the predicate device *DynaNail TTC Fusion System* (K171376) for tibio-talo-calcaneal fusion. Both the subject and predicate device achieve TTC fusion by providing sustained compression across the fusion site post-operatively.

Additionally, the *Precice® Ankle Salvage System* has the same intended use as the *Precice System* (K173129) for fracture fixation and limb lengthening.

Therefore, the differences in indications for use between the predicate devices and subject device do 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 predicates, *DynaNail TTC Fusion Syste*m (K171376), *Precice Stryde System* (K180503), and *Precice System* (K173129), which were 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	***DynaNail TTC Fusion Syste*m (K171376)**	***Precice Stryde System* (K180503)**

Intended Use	TTC Fusion	Fracture Fixation and Limb Lengthening
Summary of the subject device technology <u>similarities</u> to the predicate device	Principle of Operation: sustained compression across the fusion site Similarities in Geometry: similar implant design similar screw length and style (headed & headless)	Principle of Operation: distraction osteogenesis Material Composition: Stainless Steel
Summary of the subject device technology <u>differences</u> to the predicate device	Differences in Geometry: subject nail offered in larger diameter of 13mm and longer length nails subject nail offers additional smaller and larger screw diameters of the same length subject nail is offered with a threaded distal end subject nail uses internal gears and magnetic coupling instead of nitinol compressive elements	Differences in Geometry: subject nail is offered with a threaded distal end subject nail offers additional larger screw diameter and lengths subject nail offers a shorter total stroke length for limb lengthening

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. Additionally, a cadaver lab was performed to address creation of osteotomy around the nail.

The following testing was performed:

Testing Description	Applicable Standard
Dynamic Compression Bending Strength	ASTM F1264 - *Standard Specification and Test Methods for Intramedullary Fixation Devices*
Axial Pullout Strength	ASTM F543 - *Standard Specification and Test Methods for Metallic Medical Bone Screws*
Insertion Torque	
Torque Resistance	
Distraction and Retraction Force	N/A

The results demonstrate that the subject *Precice Ankle Salvage System* is substantially equivalent to the predicates.

I. Conclusions

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