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

December 15, 2023

Re: K232267
Trade/Device Name: Precice Max System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary Fixation Rod
Regulatory Class: Class II
Product Code: HSB, HWC
Dated: November 17, 2023
Received: November 17, 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 (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.

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,

Farzana Sharmin -S
Digitally signed by Farzana Sharmin -S
Date: 2023.12.15 12:11:41 -05'00'

Farzana Sharmin, PhD
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)*
K232267

Device Name
Precice Max System

Indications for Use *(Describe)*
The Precice Max System is indicated for limb lengthening, open and closed fracture fixation, pseudoarthrosis, mal-unions, non-unions, 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).

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 Title 21 CFR §807.92, the following summary of information is provided:

A. Submitted by:

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

Date Prepared: July 28, 2023

B. Device Name

Trade or Proprietary Name:	*Precice Max System*
Common or Usual Name:	Rod, Fixation, Intramedullary and Accessories
Classification Name:	Intramedullary Fixation Rod
Device Class:	Class II
Classification:	21 CFR § 888.3020 / 888.3040
Product Code:	HSB, HWC

C. Predicate Devices

The subject *Precice Max System* is substantially equivalent to the Precice Intramedullary Limb Lengthening System (K220234).

Primary Predicate

Product Name	510(k) Number	Date of Clearance
Precice Intramedullary Limb Lengthening System	K220234	3/15/2023

Reference Predicates

Product Name	510(k) Number	Date of Clearance
Precice Ankle Salvage System	K200430	09/16/2020
Precice Screws	K193617	05/08/2020

D. Device Description

The subject *Precice Max System* has identical indications for use as the predicate *Precice Intramedullary Limb Lengthening System (*K220234*)*, which is indicated for limb lengthening, open and closed fracture fixation, pseudoarthrosis, mal-unions, non-unions, and bone transport of long bones in 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). The subject system is designed to achieve limb correction through gradual lengthening or compression and provide intramedullary fixation for fractures of long bones. The *Precice*

Max System includes similar devices as within the predicate *Precice Intramedullary Limb Lengthening System* (K220234): nail, endcaps, locking screws, surgical instruments, and remains compatible with the external remote controllers (ERC) (ERC 1, cleared via K113219; ERC 2P, cleared via K131490; or ERC 3P, cleared via K170169; or ERC 4P, cleared via K202348). The Precice Max intramedullary nail is available in various designs, lengths, and screw hole configurations to accommodate a variety of patient anatomies and implantation methods. The screws are also available in a variety of different lengths and diameters. The subject device components are manufactured from medical grade titanium alloy per ASTM F136 Standard Specification for Wrought Titanium-6Aluminum- 4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401). The *Precice Max* nail is implanted using locking screws and reusable surgical instruments.

E. Indications for Use

The *Precice Max System* is indicated for limb lengthening, open and closed fracture fixation, pseudoarthrosis, mal-unions, non-unions, 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).

F. Technological Characteristics

As was established in this submission, the subject *Precice Max System* is substantially equivalent to the predicate, *Precice Intramedullary Limb Lengthening System (*K220234) 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 predicate through comparison in areas including clinical use, labeling/intended use, material composition, and function.

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

Intended Use	The *Precice Max System* is indicated for limb lengthening, open and closed fracture fixation, pseudoarthrosis, mal-unions, non-unions, 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).
Primary Predicate	Precice Intramedullary Limb Lengthening System (K220234)
Explanation of <u>differences</u> in Intended Use	The subject device, *Precice Max System* has the identical intended and indications for use as the *Precice Intramedullary Limb Lengthening System (*K220234*).*
Summary of the technology <u>similarities</u> to the predicate device	• Principle of Operation: Distraction osteogenesis. • Material Composition: Titanium. • Design: Magnetic mechanism

	• Accessories: Locking screws, end caps, surgical instrumentation and ERC
Summary of the technology differences to the predicate device	• Device nail offers a larger nail diameter • Device offers larger screw diameter

G. Performance Data

Nonclinical performance verification testing was performed to demonstrate that the subject Precice Max System is substantially equivalent to the predicate device, *Precice Intramedullary Limb Lengthening System (*K220234). The following table describes summary testing performed from the predicate device to establish substantial equivalence:

Testing Description	Explanation of Substantial Equivalence
Static Compression Bending Strength	ASTM F1264 – *Standard Specification and Test Methods for Intramedullary Fixation Devices*
Dynamic Compression Bending Strength	
Torsion	
Dynamic 3-Point Bending	
Torque Resistance	ASTM F543 – *Standard Specification and Test Methods for Metallic Medical Bone Screws*
Axial Pullout Strength	
Tensile Strength	N/A
Distraction Force	
Wear Debris Testing	
Corrosion Testing	

The results demonstrate that the subject Precice Max System is substantially equivalent to the predicate.

H. Conclusions

Based on the indications for use, technological characteristics, performance testing, and comparison to predicate device, the subject *Precice Max System* has been shown to be substantially equivalent to the legally marketed predicate device.