NuVasive Specialized Orthopedics, Inc.
Madison Heffron
Sr. Regulatory Affairs Specialist
101 Enterprise, Suite 100
Aliso Viejo, California 92656

March 15, 2023

Re: K220234
Trade/Device Name: Precice Intramedullary Limb Lengthening System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: March 6, 2023
Received: March 9, 2023

Dear Madison Heffron:

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: 2023.03.15 17:11:59 -04'00'

For Jiping Chen, MD, Ph.D., M.P.H.
Division 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)*

K220234

Device Name

Precice Intramedullary Limb Lengthening System

Indications for Use *(Describe)*

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).

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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Precice Intramedullary Limb Lengthening 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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Date Prepared: March 15, 2023

B. Device Name

Trade or Proprietary Name: Precice Intramedullary Limb Lengthening 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 Intramedullary Limb Lengthening System* is substantially equivalent to the following predicate devices:

For indications in an adult population, the Precice Intramedullary Limb Lengthening System is substantially equivalent to the predicate device *Precice System* (K172628).

For indications in a pediatric population (greater than 12 years old), the Precice Intramedullary Limb Lengthening System is substantially equivalent to the predicate device *FITBONE® TAA* (K203399).

D. Device Description

The predicate system is designed to achieve limb correction through gradual lengthening or compression and provide intramedullary fixation for fractures of long bones. **The purpose of**

submission is to add the treatment of pediatric patients (greater than 12 years old) to this the *Precice Intramedullary Limb Lengthening System* indications for use. The *Precice Intramedullary Limb Lengthening System* includes the same devices as within the predicate Precice System (K172628)[1]: nail, cortical screws, surgical instruments, and remains compatible with the external remote controllers (ERC) (ERC 1, in K113219; ERC 2P, in K131490; or ERC 3P, in K170169; or ERC 4P, in K191336). The configurations of sets and geometry of previously cleared Precice System devices remain unchanged. The following system description is herein repeated from K172628: Precice 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 thread styles. The ERC is available in several compatible models, including the ERC 1, ERC 2P, ERC 3P and ERC 4P. 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 IMLL nail is implanted using locking screws and reusable surgical instruments.

E. Indications for Use

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).

F. Comparison of Technological Characteristics with the Predicate Device

As was established in this submission, for adult patients, the subject *Precice Intramedullary Limb Lengthening System* is substantially equivalent to the predicate, *Precice System (*K172628) previously cleared by the FDA for commercial distribution in the United States. For pediatric patients greater than 12 years old, the subject device is substantially equivalent to the FITBONE® TAA (K203399). The subject device has been shown to be substantially equivalent and have equivalent technological characteristics to the predicates through comparison in areas including clinical use, labeling/intended use, material composition, and function. The subject device is intended for use with pediatric (greater than 12 years old) and adult patients. Safety and effectiveness for limb lengthening of intended patient population of subject device can be determined by the device's ability to perform as intended demonstrated within the submission through a retrospective study and a clinical literature analysis of pediatric patients.

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

	Subject Device	K172628 Predicate	K203399 Predicate
Indications for Use	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).	The *Precice Intramedullary Limb Lengthening System* is indicated for limb lengthening, open and closed fracture fixation, pseudoarthrosis, mal-unions, non-unions, or bone transport of long bones in patients 18 years and older.	The WITTENSTEIN intens GmbH FITBONE TAA intramedullary lengthening system is intended for limb lengthening of the femur and tibia. The FITBONE TAA intramedullary lengthening system is indicated for adult and pediatric (greater than 12 through 21 years of age) patients.
Predicates	Precice System (K172628) (Primary – patients 18 years and older) FITBONE® TAA (K203399) (Primary – pediatric patients greater than 12 years old)		
Explanation of differences in Indications for Use	The subject device is indicated for use in patients 18 years and older and pediatric patients (greater than 12 years old) patients.	The predicate device is indicated for use in all long bones of patients 18 years and older.	The predicate device is indicated for use in the femur and tibia in adult and pediatric (greater than 12 through 21 years of age) patients.
Summary of the technology similarities to the predicate device	• Principle of Operation: Distraction osteogenesis. • Material Composition: Titanium. • Design: Identical to primary predicate Precice System (K172628). • Use of External Remote Controller (ERC). • Distraction and compression.	• Principle of Operation: Distraction osteogenesis. • Material Composition: Titanium. • Use of External Remote Controller (ERC). • Distraction and compression.	• Principle of Operation: Distraction osteogenesis. • Material Composition: Stainless Steel.
Summary of the technology differences to the predicate device	• Identical to K172628.	• No design changes have been introduced as part of this submission.	• Use of an implanted receiver to receive energy from a controller. • Distraction only device (no ability for compression).

G. Performance Data

The *Precice Intramedullary Limb Lengthening System* is substantially equivalent to perform limb lengthening demonstrated by predicate device testing identical to the predicate *Precice System (*K172628). There have been no design changes introduced as part of this submission. The

purpose of this submission is to expand the indications for use of the *Precice Intramedullary Limb Lengthening System* to include its use in the treatment of pediatric patients (greater than 12 years old).

Non-clinical testing was presented to demonstrate substantial equivalence for the subject *Precice Intramedullary Limb Lengthening System*. The following testing was performed:

- Biocompatibility evaluation per ISO 10993-1, including chemical characterization per ISO 10993-18 and toxicological risk assessment per ISO 10993-17
- Wear Debris Testing
- Mechanically Assisted Crevice Corrosion (MACC) Testing

As the subject *Precice Intramedullary Limb Lengthening System* (K220234) device is identical to the predicate *Precice Intramedullary Limb Lengthening System* (K172628) device in design, material, and manufacturing, there are no new or increased risks related to biocompatibility of the subject device when compared to the predicate.

Additionally, a retrospective study and a clinical literature analysis of pediatric patients treated with the subject devices were performed. The *Precice* pediatric literature included 227 patients with 253 lengthened bones (188 femur, 53 tibia, 12 humerus) with a mean age of 14.4 years (range: 3.5-21.3 years). The retrospective study data provided clinical and radiographic data from 59 patients treated in the United States with the *Precice Intramedullary Limb Lengthening System*. The study population included 32 boys and 27 girls, with a mean age of 15.8 years (range: 12-20 years). There were 59 patient ages 13-20 years, with 43 femoral and 16 tibial lengthenings. Any potential hazards of the changes introduced as part of this submission have been evaluated and controlled through risk management activities, and any relevant information, have been addressed in the subject device labeling, after all control measures have been implemented.

Table 1. Pediatric Literature Review

Population	**Pediatric**		**Adult**
Data Source	Literature	Retrospective Study	Literature
Group	All	13-20 years	All
Demographic Information			
N (bones)	227 (253)	59 (59)	136 (189)
Age, mean (range)	14.4 (3-21)	15.8 (13-20)	36.1 (21-74)
Gender, male/female, %	52.5/47.5	54.2/45.8	69.7/30.4
Etiology: congenital/acquired, %	52.9/47.1	86.4/13.6	11.6/88.4
Limb length discrepancy, cm	5.3	4.9	4.9
Target length, cm	6.2	4.9	4.7
Achieved length, mean, cm	5.5	4.6	5.4
Achieved length/target, overall, %	93.0	93.9	119.5
Achieved length/target, femoral, %	114.6	94.1	127.5
Achieved length/target, tibial, %	93.0	90.7	110.0
Bone healing rate, %	100.0	100.0	94.3%
Adverse Events			
Device-related adverse events	6.7%	6.8%	22.2%
Lengthening-related adverse events	16.6%	34.7%	8.5%
Joint loss of ROM*	6.2%	3.4%	2.9%
Joint subluxation/dislocation*	4.0%	3.4%	0.0%
Angular malalignment*	2.8%	1.7%	0.0%
Radiographic – premature consolidation	1.8%	3.4%	2.2%

Population	**Pediatric**		**Adult**
Data Source	Literature	Retrospective Study	Literature
Group	All	13-20 years	All
Radiographic – delayed union	2.6%	16.9%	8.1%
Radiographic – partial union	0.0%	3.4%	0.0%
Radiographic – nonunion	0.9%	5.1%	5.1%

* Clinically significant events, i.e., those requiring major surgical treatments.

H. Conclusions

The subject *Precice Intramedullary Limb Lengthening System* has been shown to be substantially equivalent to the legally marketed predicate devices for its intended use.