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

November 7, 2019

Re: K192181
Trade/Device Name: PRECICE Plating System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: KTT, HRS, HWC
Dated: August 7, 2019
Received: August 12, 2019

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,

For: Shumaya Ali
Assistant Director
DHT6C: Division of Restorative, Repair,
and Trauma 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)*

K192181

Device Name

PRECICE® Plating System

Indications for Use *(Describe)*

The PRECICE® Plate System is indicated for limb lengthening, open and closed fracture fixation, pseudoarthrosis, mal-unions and non-unions of long bones in pediatrics and small stature adult patients.

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 Plating 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:

Madison Heffron
Regulatory Affairs Specialist
NuVasive Specialized Orthopedics, Inc.
101 Enterprise, Suite 100
Aliso Viejo, CA 92656
Telephone: (949) 532-7868

Date Prepared: November 6, 2019

B. Device Name

Trade or Proprietary Name:	*PRECICE® Plating System*
Common or Usual Name:	Appliance, Fixation, Nail/Blade/Plate Combination, Multiple Component
Classification Name:	Single/multiple component metallic bone fixation appliances and accessories
Device Class:	Class II
Classification:	21 CFR § 888.3030
Product Code:	KTT, HRS, HWC

C. Predicate Devices

The subject *PRECICE Plate System* is substantially equivalent to the following predicate devices;

For limb lengthening, the Precice Plate System is substantially equivalent to the predicate device *Inter-Os Limb Lengthener* (K031875),

For fracture fixation, including open and closed fracture fixation, pseudoarthrosis, mal-unions and non-unions, the Precice Plate System is substantially equivalent to the predicate device *Orthopediatrics Fracture and Osteotomy Bone Plate System* (K111086),

In addition, the following reference devices were used to establish substantial equivalence, *PRECICE STRYDE* (K180503) and *Orthofix Modulsystem* (K955848).

D. Device Description

The *PRECICE Plating System* includes the PRECICE plate, cortical screws, surgical instruments, and is compatible with an external remote controller (ERC). The PRECICE plate is supplied sterile by gamma radiation while the cortical screws and instruments are supplied non-sterile and must be sterilized prior to use. The system is designed to achieve limb correction through gradual lengthening or compression and providing internal fixation for fractures of long bones. The telescopic PRECICE plate is implanted using cortical screws and reusable surgical instruments.

The PRECICE plate contains an enclosed rare earth magnet, telescoping distraction rod, and planetary gearing which allows the length of the plate to be adjusted non-invasively by the External Remote Controller (ERC). The PRECICE Plate is available in various sizes, lengths and screw hole configurations to accommodate a variety of patient anatomies and implantation methods. The cortical screws are also available in a variety of lengths and thread styles. The ERC is available in several compatible models.

The purpose of this premarket notification is to market the new device PRECICE Plating System.

E. Indications for Use

The PRECICE Plate System is indicated for limb lengthening, open and closed fracture fixation, pseudoarthrosis, mal-unions and non-unions of long bones in pediatrics and small stature adult patients.

F. Comparison of Indications for Use with the Predicate Device

The Precice Plate System is substantially equivalent to the *Inter-Os Limb Lengthener (*K031875) for limb lengthening. The subject device is intended for use with pediatric and small stature adults compared to the predicate indicated for adults. Safety and effectiveness for limb lengthening of intended patient population of subject device can be determined by the device's ability to provide stability to the osteotomy site and to provide adequate force for distraction osteogenesis. The subject device is intended for use in all long bones compared to the predicate device indicated for the femur only. Differences in long bone placement present similar risks for surrounding soft tissue interaction and mechanical performance. Safety and effectiveness of the device is acceptable when used in accordance with labeling detailed to address each long bone specific anatomy. The differences between the subject device and predicate device are not critical for limb lengthening of long bones in adults, small stature adults and pediatric patients.

Additionally, the PRECICE Plate System has the same intended use as *Orthopediatrics Fracture and Osteotomy Bone Plate System* (K111086) for fracture fixation.

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 Plating System* is substantially equivalent to the predicates, *Inter-Os Limb Lengthener (*K031875) and *Orthopediatrics Fracture and Osteotomy Bone Plate System* (K111086), and reference predicates *PRECICE STRYDE* (K180503) and *Orthofix Modulsystem* (K955848), 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, 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:

Intended Use	Limb Lengthening of Long Bones	Fracture fixation of Long Bones
Primary Predicate	*Inter-Os Limb Lengthener (*K031875)	*Orthopediatrics Fracture and Osteotomy Bone Plate System* (K111086)
Reference Device	*PRECICE STRYDE* (K180503) and *Orthofix Modulsystem* (K955848)	*PRECICE STRYDE* (K180503)
Summary of the technology <u>similarities</u> to the predicate device	• Principle of Operation: Distraction osteogenesis. • Material Composition: Stainless steel • Similar compatible screw sizes • Similar distracting plate mechanism • Intended to be removed after bone consolidation	• Principle of Operation: Fixation and osteotomy lengthening. • Material Composition: Stainless steel • Similar compatible screw sizes • Similar implant shape and design • Non-weight bearing
Summary of the technology <u>differences</u> to the predicate device	• The maximum stroke length for the PRECICE Plate is less than the predicate. The PRECICE Plate contains less screw holes than the predicate. • Use of ERC with PRECICE Plate provides distraction of plate non-invasively compared to predicate device which uses a percutaneous handle.	• The PRECICE Plate has a greater profile than the predicate device. • Use of ERC with PRECICE Plate provides compression non-invasively after index procedure compared to predicate which can only provide compression through compression slots intraoperatively.

H. Performance Data

Nonclinical performance verification testing was performed to demonstrate that the subject *PRECICE Plating System* is substantially equivalent to the predicate devices.

The PRECICE Plate System is substantially equivalent to perform limb lengthening demonstrated by preclinical testing. Safety and effectiveness was also demonstrated by engineering analysis to support substantial equivalence of the subject device to the *Inter-Os Limb Lengthener (*K031875), *Orthofix Modulsystem* (K955848) and clinical literature.

The PRECICE Plate System is substantially equivalent to perform fracture fixation demonstrated by predicate device testing of *Orthopediatrics Fracture and Osteotomy Bone Plate System* (K111086) to ASTM F384 and ASTM F543.

The following table describes summary testing performed and incorporated by reference from predicate devices to establish substantial equivalence:

Testing Description	Predicate Device	Explanation of Substantial Equivalence
Static Compression Bending Strength per ASTM F384	*Orthofix Modulsystem* (K955848) and *Orthopediatrics Fracture and Osteotomy Bone Plate System* (K111086)	Bending load on construct of subject device performs substantially equivalent under the same loading conditions as predicate devices.
Dynamic Compression Bending strength per ASTM F384		
Engineering Analysis of Bending Construct	*Orthofix Modulsystem* (K955848)	Characterization of an offset bending load of the subject device was demonstrated to perform substantially equivalent to the predicate device.
Torque Resistance per ASTM F543	*Orthofix Modulsystem* (K955848) and *Orthopediatrics Fracture and Osteotomy Bone Plate System* (K111086)	Characterization of torque resistance of subject device is substantially equivalent to the predicate devices.
Axial Pullout per ASTM F543		Characterization of screw pullout force is substantially equivalent to the predicate devices.
Torsion	*Orthofix Modulsystem* (K955848) and *PRECICE STRYDE* (K180503)	Characterization of torsional strength of subject device is substantially equivalent to the predicate devices.
Tensile and Collapse Strength	*Inter-Os Limb Lengthener* (K031875) and *Orthofix Modulsystem* (K955848)	Subject device resists tensile loads substantially equivalent to the predicate devices.
Distraction Force	*PRECICE STRYDE* (K180503) and clinical literature	Distraction force is substantially equivalent to the predicate device.

The results demonstrate that the subject *PRECICE Plating System* is substantially equivalent to the predicates.

I. Conclusions

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