NuVasive Specialized Orthopedics, Inc.
Vidhi Bhatt
Regualtory Affairs Specialist
101 Enterprise, Suite 100
Aliso Viejo, California 92656

February 5, 2019

Re: K182170
Trade/Device Name: PRECICE® BONE TRANSPORT™ System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary Fixation Rod
Regulatory Class: Class II
Product Code: HSB, HWC
Dated: September 21, 2018
Received: September 24, 2018

Dear Vidhi Bhatt:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Daniel S. Ramsey -S
2019.02.05 16:31:33 -05'00'

FOR Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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)*
K182170

Device Name

PRECICE® BONE TRANSPORT™ System

Indications for Use *(Describe)*

The PRECICE® BONE TRANSPORT™ System is indicated for limb-lengthening, open and closed fracture fixation, pseudoarthrosis, mal-unions, non-unions or bone transport of long bones.

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® Bone Transport System
510(k) Summary – K182170

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:

Vidhi Bhatt
Regulatory Affairs Specialist
NuVasive Specialized Orthopedics, Inc.
101 Enterprise, Suite 100
Aliso Viejo, CA 92656
Telephone: (949) 563-0655

Date Prepared: February 5, 2019

B. Device Name

Trade or Proprietary Name:	PRECICE® Bone Transport System
Common or Usual Name:	Intramedullary Fixation Rod
Classification Name:	Rod, Fixation, Intramedullary and Accessories; Screw, Fixation, Bone
Device Class:	Class II
Classification:	21 CFR § 888.3020
Product Code:	HSB, HWC

C. Predicate Devices

Predicate Device	PRECICE® System (K173129)
Reference Device	PRECICE® Stryde System (K180503)

D. Device Description

The *PRECICE® Bone Transport System* includes the *PRECICE® Bone Transport* Nail, locking screws, end caps, surgical instruments, and external remote controller (ERC). The *PRECICE® Bone Transport* nails and end caps are supplied sterile by gamma radiation while the locking 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 of the intercalary bone segment and providing internal fixation for fractures of long bones. The *PRECICE® Bone Transport* intramedullary nail is implanted using locking screws, end caps, and reusable surgical instruments. The *PRECICE® Bone Transport* nail contains an enclosed rare earth magnet, distraction rod, and planetary gearing which allows the extension of the distraction rod to be adjusted non-invasively by the External Remote Controller (ERC). The *PRECICE® Bone Transport* nail is available in various diameters, lengths and screw hole configurations to accommodate a variety of patient anatomies and implantation methods. The locking screws are also available in a variety of diameters, lengths, and thread styles. The ERC is available in several compatible models.

The purpose of this submission is to implement design changes to the predicate *PRECICE® System* (K173129) and reference device *PRECICE® Stryde System* (K180503) to create a product line extension which includes the *PRECICE® Bone Transport* nail and compatible locking screws and end caps. The subject nail performance meets predicate device performance specifications. The design changes of subject nail inform revised contraindications, warnings, precautions and implantation procedure on the label to address new risks compared to predicate device.

These modifications to the *PRECICE® System* 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. Indication for Use

The *PRECICE® Bone Transport System* is indicated for limb lengthening, open and closed fracture fixation, pseudoarthrosis, mal-unions, non-unions, or bone transport of long bones.

F. Comparison of Technological Characteristics with the Predicate Device

The subject *PRECICE® Bone Transport System* is substantially equivalent to the predicate *PRECICE® System* (K173129) and reference device *PRECICE® Stryde System* (K180503) previously cleared by the FDA for commercial distribution in the United States.

Substantial equivalence between subject, predicate and reference device is established based on identical indications for use, material composition, technological characteristics, principles of operation and fundamental scientific principles.

Substantial equivalence is also based on device dimension, specifically, the nail diameters, locking screws, device configurations and end caps which are the same as the reference device. The predicate, reference and subject devices are inserted into the intramedullary canal of the long bones and secured with locking screws. The predicate, reference and subject devices are adjusted non-invasively by the External Remote Controller (ERC). The design modifications for the subject device, PRECICE® Bone Transport are as follows:

- The subject nail is a slotted intramedullary (IM) nail. The housing tube of this IM nail has longitudinal transport slot.
- The stroke length/transport length is independent of rod length since the distraction rod excursion is accommodated within the housing tube making the subject device a fixed length device.
- The distraction rod spans both the defect site and osteotomy site.
- Additional size of locking screw available with the subject device
- Assembly of the gear train and distraction rod is reversed to incorporate the transport slot although the components remain the same as the predicate device

The labeling changes includes added contraindication and warning based on the design modifications of the subject device.

There are no changes being made to the ERCs or PRECICE® surgical instruments as a result of this submission.

Conclusions can be drawn from these comparisons that the subject *PRECICE® Bone Transport System* is substantially equivalent to the predicate device.

G. Performance Data

Nonclinical performance verification testing was performed to demonstrate that the subject *PRECICE® Bone Transport System* is substantially equivalent to the predicate PRECICE® device. The following testing shows that the subject device conforms to the following standards, practices and guidance:

Testing Description	Applicable Standard
Static Compression Bending Strength	ASTM F1264 - *Standard Specification and Test Methods for Intramedullary Fixation Devices*
Dynamic Compression Bending strength	
Torsion	
Torque Resistance	ASTM F543 - *Standard Specification and Test Methods for Metallic Medical Bone Screws*
Axial Pullout	
Biocompatibility	ISO 10993- Biological evaluation of medical devices
Sterilization	Gamma Irradiation Sterilization Testing: VDmax 25 kGy method per IS/EN/ISO 11137-1:2015 and IS/EN/ISO 11137-2:2015
Package Distribution	ASTM D4169-16 Standard Practice for Performance Testing of Shipping Containers and Systems

In addition, the device also underwent the following performance testing to show that all requirements have been met:

- Distraction Force Testing
- Retention Force Testing
- Fluid Ingress Testing
- Biomechanical Axial Compression Testing

The results demonstrate that the subject *PRECICE® Bone Transport System* is substantially equivalent to the predicate device.

H. Conclusions

The subject *PRECICE® Bone Transport System* has been shown to be substantially equivalent to the legally marketed predicate device for its intended use.