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

Re: K191336
Trade/Device Name: PRECICE System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary Fixation Rod
Regulatory Class: Class II
Product Code: HSB, HWC
Dated: August 29, 2019
Received: August 30, 2019

Dear Aditya Sharma:

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, M.P.H.
Assistant Director
DHT6C: Division of Stereotaxic, Trauma
and Restorative 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)*
K191336

Device Name
PRECICE® System

Indications for Use *(Describe)*
The PRECICE® 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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

**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:

Aditya Sharma
Sr. Regulatory Affairs Specialist
NuVasive Specialized Orthopedics Incorporated
101 Enterprise, Suite 100
Aliso Viejo, California, 92656
Telephone: (949) 837-3600.

Date Prepared: August 29, 2019

## B. Device name

| | |
|---|---|
| Proprietary Name: | PRECICE® System |
| Common or Usual Name: | Intramedullary Fixation Rod, Smooth or threaded metallic bone fixation fastener |
| Classification Name: | Rod, Fixation, Intramedullary and Accessories |
| Regulation Number: | 21 CFR § 888.3020, 21 CFR 888.3040 |
| Classification: | Class II |
| Product Code (primary): | HSB |
| Product Code (subsequent): | HWC |

## C. Predicate Devices

The subject PRECICE® System is substantially equivalent to the primary predicate device, PRECICE® Intramedullary Limb Lengthening System (K170169) and additional predicate devices, PRECICE® System (K173129) and PRECICE® Stryde (K180503).

## D. Device Description

The PRECICE® System is composed of the PRECICE® Nail, locking screws, end cap, surgical instruments and an external remote controller (ERC). The Nail is available in various diameters, lengths and screw hole configurations to accommodate a variety of patient anatomies. The locking screws are also available in a variety of diameters and lengths. The PRECICE® Nail and end cap is supplied sterile by gamma radiation while the locking screws and reusable instruments are supplied non sterile and must be sterilized prior to use. The Nail contains an enclosed rare earth magnet, telescoping lead screw/nut assembly, and planetary gearing. The Nail is offered in pre-distracted and non-predistracted models. Pre-distracted models are supplied pre-distracted by 10 mm (femur and, tibia models), 15 mm and 20 mm (humeral model), to allow for compression fracture reduction techniques.

The PRECICE® Stryde System includes the PRECICE® Stryde Nail, locking screws, end caps, surgical instruments, and external remote controller (ERC). The PRECICE® Stryde 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 and providing internal fixation for fractures of long bones. The telescopic PRECICE® Stryde Nail is implanted using locking screws, end caps, and reusable surgical instruments. The PRECICE® Stryde 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 External Remote Controller (ERC). The PRECICE® Stryde 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 reason for this submission is to introduce some design modifications to the third generation of the External Remote Controller (ERC 3P) cleared under K170169. The subject device, ERC 4P, is fourth generation of ERC component of the PRECICE® System.

## E. Indications for Use

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

## F. Technological Characteristics

As was established in this submission, the subject PRECICE® System is substantially equivalent to the predicate device cleared by the FDA for commercial distribution in the United States. The subject device was shown to be substantially equivalent and have equivalent technological characteristics to its predicate devices through comparison in areas including design, intended use, material composition, and functions.

## G. Performance Data

Nonclinical testing was performed to demonstrate that the subject PRECICE® System is substantially equivalent to predicate devices. Following testing have been included in the submission to show substantial equivalence to the predicate device.

| Test | Applicable standard |
|---|---|
| Electrical Safety | IEC 60601-1 (3rd edition): 2005 |
| Electromagnetic Compatibility and Interference | IEC 60601-1-2: 2014 |
| Minimum rated voltage testing | IEC 60601-1-11:2015 |
| Shock and Vibration Testing | |
| Ingress protection | |

| Test | Applicable standard |
|---|---|
| Magnet Safety Analysis | N/A |
| Usability Study | N/A |
| Labeling Readability | N/A |

## H. Conclusions

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