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

December 1, 2017

Re: K173129
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: November 14, 2017
Received: November 15, 2017

Dear Lance Justice:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Mark N. Melkerson -S

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: January 31, 2017
See *PRA Statement below.*

51O(k) Number *(if known)*

K173129

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.

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NUVASIVE
SPECIALIZED ORTHOPEDICS, INC.™

PRECICE System
510(k) Summary – K173129

1. **Company:** NuVasive Specialized Orthopedics, Inc.
101 Enterprise, Suite 100
Aliso Viejo, CA 92656

Contact: Lance Justice
Regulatory Affairs Specialist
Phone: (949) 544-6540
Fax: (949) 837-3664

Date Prepared: November 14, 2017

2. **Proprietary Trade Name:** PRECICE System

3. **Classification Name:** Intramedullary Fixation Rod (21 CFR 888.3020)

Smooth or threaded metallic bone fixation fastener (21 CFR 888.3040)

4. **Product Code:** HSB (Rod, Fixation, Intramedullary and Accessories)

HCW (Screw, Fixation, Bone)

5. **Product 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 screwhole 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-pre-distracted 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

6. **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.

7. **Substantial Equivalence:** The subject PRECICE System is substantially equivalent to the most recently cleared PRECICE System (K172628). Substantial equivalence is based on

indications for use, technological characteristics, and principles of operation. In addition, the Cannulated Screw System (K003496) by Pioneer is designated as a reference device to further substantiate equivalence of the material change to include stainless steel Biodur 108.

Substantial equivalence is based on identical indications for use, design, technological characteristics, principles of operations, and fundamental scientific principles. The Risk Management file was updated to include the material modification and no new risks were identified.

Other than the material change described in the submission, there are no changes to the design of the devices. The additional stainless steel PRECICE nails are available in the same application, screwhole configurations, stroke lengths, and overall lengths. The additional stainless steel locking screws are also available in the same thread styles, lengths, and diameters. The additional stainless steel end caps are available in the same sizes. No changes are being made to the design, technological characteristics or principles of operation as a result of this premarket notification. Both devices are inserted into the intramedullary canal of the long bones and secured with locking screws. Both devices are adjusted non-invasively by the External Remote Controller. The differences between the subject device and the predicate device are as follows:

- Extension of the product offering to include PRECICE Nails, locking screws, and end caps composed of stainless steel
- Material change of the patient contacting components of the PRECICE Nail to stainless steel (Biodur 108).
- Material change of the locking screws to stainless steel (Biodur 108).
- Material change of the end caps to stainless steel (Biodur 108).

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

The subject PRECICE System and the predicate device have the same indications for use. Specifically, both systems are indicated for limb lengthening, open and closed fracture fixation, pseudoarthrosis, mal-unions, non-unions, or bone transport of long bones.

The subject PRECICE System has the same technological characteristics and the same principles of operation as that of the predicate system. The technological characteristics and design of the subject PRECICE Nails, end cap, instruments, and External Remote Controllers are identical to the predicate device. All testing previously performed on these components of the predicate system (i.e. PRECICE Nail, end cap, and External Remote

Controllers) are applicable to this submission. The difference between the two systems is a change in material to include intramedullary nails, locking screws, and end caps composed of stainless steel.

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