NuVasive Specialized Orthopedics, Inc.  
Cora Sim  
Associate Manager, Regulatory Affairs  
101 Enterprise, Suite 100  
Aliso Viejo, California 92656  

Re: K172628  
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 31, 2017  
Received: September 1, 2017

Dear Ms. Sim:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

**Katherine D. Kavlock -S**

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
510(k) Number (if known)
K172628

Device Name
PRECICE System

Indications for Use (Describe)
The PRECICE System is indicated for limb lengthening, open and closed fracture fixation, pseudoarthrosis, malunions, 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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1. **Company:** NuVasive Specialized Orthopedics, Inc.  
   101 Enterprise, Suite 100  
   Aliso Viejo, CA 92656

2. **Contact:** Cora Sim  
   Associate Manager, Regulatory Affairs  
   Phone: (949) 544-6478  
   Fax: (949) 837-3664

**Date of Submission:** September 15, 2017

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

4. **Classification Name:**  
   - Intramedullary Fixation Rod (21 CFR 888.3020)  
   - Smooth or threaded metallic bone fixation fastener (21 CFR 888.3040)

5. **Product Code:**  
   - HSB (Rod, Fixation, Intramedullary and Accessories)  
   - HWC (Screw, Fixation, Bone)

6. **Product Description:** The PRECICE System is composed of the PRECICE Nail (supplied sterile), locking screws, end cap, surgical instruments and an external remote controller (ERC). The Nail is available in various diameters, lengths and screwwhole 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.

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

8. **Substantial equivalence:** A detailed comparison to the predicate device demonstrates that the PRECICE System is substantially equivalent to the following 510(k) cleared device:
Trade Name: PRECICE UNYTE System
Common Name: Intramedullary Fixation Rod
510(k) Clearance Number: K172061

In addition, the PRECICE System designates the following 510(k) cleared reference devices:

<table>
<thead>
<tr>
<th>Trade Name</th>
<th>Common Name</th>
<th>510(k) Clearance Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>PRECICE Intramedullary Limb Lengthening System</td>
<td>Intramedullary Fixation Rod</td>
<td>K170346</td>
</tr>
<tr>
<td>PRECICE UNYTE System</td>
<td>Intramedullary Fixation Rod</td>
<td>K170169</td>
</tr>
<tr>
<td>PRECICE UNYTE CoCr System</td>
<td>Intramedullary Fixation Rod</td>
<td>K160267</td>
</tr>
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Substantial equivalence is based on indications for use, technological characteristics, and principles of operation.

The PRECICE System subject to this 510(k) and the predicate device have similar 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 PRECICE Intramedullary Limb Lengthening System and PRECICE UNYTE System reference devices listed above both utilize the same device. The PRECICE UNYTE CoCr System reference device listed above includes limb lengthening along with open and closed fracture fixation, pseudoarthrosis, mal-unions and non-unions within it indications for use. This 510(k) is intended to align the indications of the PRECICE System with the predicate device in the PRECICE family and in the same product code by including open and closed fracture fixation, pseudoarthrosis, or mal-unions and non-unions, or bone transport of long bones. Essentially, NSO is combining all of the models offered in the predicate device with the subject PRECICE System, as the systems are identical and utilize the same device. The subject PRECICE System will include the pre-distracted models found in the predicate device to allow for compression fracture reduction techniques.

The PRECICE System has the same technological characteristics and the same principles of operation as that of the predicate as both systems utilize the same device. The design of both intramedullary nails is identical. Both devices are inserted into the intramedullary canal of the long bone and secured with
locking screws. Both devices are adjusted non-invasively by the External Remote Controller (ERC, ERC 2P, and ERC 3P).

There are no design, technological or performance changes to the PRECICE Nail being made as a result of this submission as the PRECICE System is identical to the PRECICE UNYTE System, therefore all testing that was performed on the predicate PRECICE UNYTE Nail and PRECICE Systems previously cleared, are applicable.

There are no changes to the design of the ERCs being made as a result of this submission, therefore all testing that was performed on the ERC use with the predicate PRECICE UNYTE Nail System and the PRECICE System for the ERC are applicable.

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