DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 9, 2017

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

Re: K170169
Trade/Device Name: PRECICE Intramedullary Limb Lengthening System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary Fixation Rod
Regulatory Class: Class II
Product Code: HSB
Dated: May 23, 2017
Received: May 24, 2017

Dear Cora 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 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 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,

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.

510(k) Number *(if known)*
K170169

Device Name
PRECICE Intramedullary Limb Lengthening System

Indications for Use *(Describe)*
The PRECICE Intramedullary Limb Lengthening System is indicated for limb lengthening of the tibia and femur.

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® Intramedullary Limb Lengthening System
510(k) Summary - K170169
May 23, 2017

1. **Company:** NuVasive Specialized Orthopedics, Inc.
101 Enterprise, Suite 100
Aliso Viejo, CA 92656
Phone: (949) 837-3600
Fax: (949) 837-3664

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

Date of Submission: May 23, 2017

2. **Proprietary Trade Name:** PRECICE® Intramedullary Limb Lengthening System

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

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

5. **Product Description:** The PRECICE Intramedullary Limb Lengthening System is composed of the PRECICE Nail (supplied sterile), locking screws, end cap, surgical instruments and an external remote controller (ERC, ERC2P, or ERC 3P). The nail is available in tibia or femur models with 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 is supplied sterile by gamma radiation while the locking screws and PRECICE surgical instruments are supplied non-sterile and must be sterilized prior to use.

The third generation External Remote Controller (ERC 3P) which is the subject of this premarket notification, is a non-invasive adjustment component of the system. The ERC 3P is an electrically powered handheld unit. The ERC 3P contains two large rare-earth magnets that are rotated using gears. After the PRECICE Nail has been implanted into the patient, the external device can be placed over the actuator portion of the nail and activated. When activated, the magnets within the ERC 3P rotate, which causes the magnet in the actuator portion of the PRECICE Nail to rotate,

lengthening or shortening the nail. Periodic lengthening (typically daily) of the nail is performed after the implantation surgery to lengthen the limb. The ERC 3P also encompasses on-unit prescription programming. The distraction is confirmed in office using standard, routine x-ray of the limb. These office visits usually occur on a weekly basis. The principles of operation of the ERC 3P are the same as those of the ERC and ERC2P previously cleared.

6. **Indications:** The PRECICE Intramedullary Limb Lengthening System is indicated for limb lengthening of the tibia and femur.

7. **Substantial Equivalence:** Documentation demonstrates substantial equivalence to the PRECICE Intramedullary Limb Lengthening System cleared under K101997 (cleared on July 12, 2011), K113219 (cleared on October 19, 2012), K131490 (cleared on January 23, 2014), K133289 (cleared on December 9, 2013), K141023 (cleared on May 20, 2014), K150656 (cleared on April 23, 2015), K151131 (cleared on June 19, 2015), and most recently K160325 (cleared on April 4, 2016) . The purpose of this premarket notification is to include a third generation External Remote Controller (ERC 3P) into the PRECICE® Intramedullary Limb Lengthening System. Data provided in this submission includes information relevant to the third generation ERC (ERC 3P). Substantial equivalence is based on similar indications for use, designs, *in vitro* testing, software validation, and Usability and labeling readability evaluations performed. The *in vitro* evaluations included specific tests performed on the ERC 3P to demonstrate the suitability of the device for its intended use, and electrical safety and electromagnetic compatibility tests. Usability evaluation of the ERC 3P in a representative population was performed to demonstrate its suitability for use by the proposed patient population in the home environment and in accordance with the indications.

The ERC 3P was designed to improve ergonomic handling and user interfaces, and has the same methods and principles of operation as the first and second generation ERCs. The ERC 3P incorporates an updated user interface and combines the controller and hand piece into one unit, to be more ergonomic and user friendly. The ERC 3P incorporates an updated user interface that utilizes an LCD touchscreen, camera, external magnet line to assist the patient in proper alignment with the implant location, as well as features to detect the pairing status of the ERC 3P with the implanted PRECICE Nail during lengthening sessions. The third generation ERC for the PRECICE Intramedullary Limb Lengthening System was developed and evaluated in accordance with recognized standards and with in-house developed test methodologies. This testing includes risk assessment of the device, testing to applicable IEC standards, and a usability study undertaken on 17 participants to evaluate the usability of the ERC 3P in an equivalent patient population. Risk analysis, draft labeling, and test results are included in this premarket notification. The results of

testing demonstrate that the ERC 3P for the PRECICE Intramedullary Limb Lengthening System that is the subject of this premarket notification is substantially equivalent to the predicate External Remote Controller (ERC 2P) device.

The following documentation and testing have been included in order to establish equivalence to the predicate device. Testing includes a usability evaluation for the Home Use of the ERC 3P by the patient, minimum rated voltage testing, shock and vibration testing, and ingress protection testing performed in accordance with IEC 60601-1-11;2015. The following tests have been performed in order to establish equivalence to the predicate device:

Test/Document Description	Applicable test standard
Risk Management Report	EN ISO 14971: 2012
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	
Usability evaluation	N/A
Labeling Readability	N/A

Conclusions can be drawn from the testing performed that the PRECICE Intramedullary Limb Lengthening System is substantially equivalent to the predicate device.