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

March 7, 2017

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

Re: K170346
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, HWC
Dated: February 1, 2017
Received: February 2, 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.

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)*
K170346

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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PRECICE Intramedullary Limb Lengthening System
510(k) Summary

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: February 27, 2017

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

3. **Classification:** 888.3020, 888.3040

4. **Product Code:** HSB, HWC

5. **Product Description:** The PRECICE Intramedullary Limb Lengthening (IMLL) System is composed of the PRECICE Nail, locking screws, end cap, surgical instruments, and an External Remote Controller (ERC or ERC 2P). The nail is available in tibial and femoral 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, lengths, and thread styles. The PRECICE Nail is supplied sterile by gamma radiation; the locking screws and surgical instruments are supplied non sterile, and must be sterilized prior to use.

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

7. **Substantial equivalence:** The subject PRECICE IMLL System is substantially equivalent to the most recently cleared PRECICE IMLL System (K160325). Substantial equivalence is based on indications for use, technological characteristics, and principles of operation. In addition, the PRECICE Trauma Nail System (K160267) and Zimmer Natural Nail System (K083497) are designated as a reference devices to further substantiate equivalence of the new screws to be added to the system.

   The subject PRECICE IMLL System and the predicate device have the same indications for use. Specifically, both systems are indicated for limb lengthening of the tibia and the femur.

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The subject PRECICE IMLL System has similar technological characteristics and the same principle of operation as that of the predicate system. The technological characteristics of the subject PRECICE Nails, end cap, instruments, and External Remote Controller (ERC and ERC 2P) 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 Controller) are applicable to this submission. The difference between the two systems is the addition of two screw thread styles (partially threaded and fully threaded) to the currently available peg style screws of the predicate system.

There are no technological or performance changes to the PRECICE IMLL Nail being made as a result of this submission, therefore all testing previously performed on the predicate PRECICE Nail are applicable.

The assessment of substantial equivalence is based upon mechanical testing previously performed on the same screws used in the reference device system (K160267). Mechanical testing on the locking screws were previously performed according to the methods outlined in ASTM F1264-14 and ASTM F543-13.

Pyrogen testing was performed per *ANSI/AAMI ST72:2011 – Bacterial Endotoxins – Test Methods, Routine Monitoring, and Alternatives to Batch Testing* on the subject device to ensure it meets the pyrogen limit specifications for sterile implant devices.

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