DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 6, 2017

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

Re: K162927
Trade/Device Name: PRECICE UNYTE CoCr System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary Fixation Rod
Regulatory Class: Class II
Product Code: HSB
Dated: October 17, 2016
Received: October 19, 2016

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)*
K162927

Device Name
PRECICE UNYTE CoCr System

Indications for Use *(Describe)*
The PRECICE UNYTE CoCr System is indicated for open and closed fracture fixation, pseudoarthrosis, mal-unions and non-unions, or limb lengthening of the tibia.

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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510(k) Summary
PRECICE® UNYTE CoCr System
510(k) Summary – K162927
March 2, 2017

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

   Contact: Cora Sim
   Sr. Regulatory Affairs Specialist
   Phone: (949) 544-6478
   Fax: (949) 837-3664

   Date of Submission: March 2, 2017

2. **Proprietary Trade Name:** PRECICE UNYTE CoCr 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 UNYTE CoCr System is composed of the PRECICE UNYTE CoCr Nail (supplied sterile), locking screws, end cap, surgical instruments and an external remote controller (ERC). The nail is available in tibia models with various diameters and lengths to accommodate a variety of patient anatomies. The locking screws are also available in a variety of diameters, lengths, and configurations (fully and partially threaded). The PRECICE CoCr Nail and end cap are supplied sterile by gamma radiation while the locking screws and surgical 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 supplied either pre-distracted by 10 mm to allow for compression fracture reduction techniques or fully retracted for limb lengthening applications.

6. **Indications:** The PRECICE UNYTE CoCr System is indicated for open and closed fracture fixation, pseudoarthrosis, mal-unions and non-unions, or limb lengthening of the tibia.

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7. **Substantial equivalence:** A detailed comparison to the predicate device demonstrates that the PRECICE UNYTE CoCr System is substantially equivalent to the following 510(k) cleared device:

Trade Name:	PRECICE® Trauma Nail System
Common Name:	Intramedullary Fixation Rod
510(k) Clearance Number:	K160267

In addition, the PRECICE UNYTE CoCr System designates the following 510(k) cleared reference device:

Trade Name:	PRECICE® Intramedullary Limb Lengthening System
Common Name:	Intramedullary Fixation Rod
510(k) Clearance Number:	K160325

Substantial equivalence is based on indications for use, technological characteristics, principles of operation, and on *in vitro* testing performed.

The PRECICE UNYTE CoCr Nail System subject to this 510(k) and the predicate device have similar indications for use. Specifically, both systems are indicated for open and closed fracture fixation, pseudoarthrosis, or mal-unions and non-unions of the tibia. This 510(k) is intended to include additional implant sizes utilizing cobalt chromium alloy (CoCr) material and to expand the indications to include limb lengthening.

The PRECICE UNYTE CoCr System has the same technological characteristics and the same principles of operation as that of the predicate. Both devices are inserted into the intramedullary canal of the tibia and secured with locking screws. Both devices are adjusted non-invasively by the External Remote Controller (ERC).

The PRECICE UNYTE CoCr Nail has similar design features as that of the predicate. Both the PRECICE UNYTE CoCr Nail and the predicate are intramedullary nails with a telescoping portion that can adjust the length of the implant. Both devices are inserted into the intramedullary canal of the tibia and secured with locking screws. Both devices are adjusted non-invasively by the external remote controller (ERC). The overall length of the PRECICE UNYTE CoCr Nail is similar to the overall length of the predicate.

Testing of the PRECICE UNYTE CoCr System included sterilization validation, shelf life testing for packaging and device functionality, biocompatibility testing, and testing to ASTM F1264 for intramedullary rods. Pyrogen testing was also performed on the subject device to ensure it meets the pyrogen limit specifications for sterile implant devices.

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The following specific tests have been performed in order to establish equivalence to the predicate device:

Test Description	Applicable Test Standard
PRECICE, Static Four Point Bend	ASTM F1264-14
PRECICE, Dynamic Four Point Bend	ASTM F1264-14
PRECICE, Static Torque to Failure	ASTM F1264-14
25 Month Shelf Life Packaging Validation	I.S. EN ISO 11607-1
Standard Guide for Accelerated Aging of Sterile Medical Device Packages	ASTM F1984-07
Standard Test Method for Seal Strength of Flexible Barrier Materials	ASTM F88/F88M-09
Standard Practice for Performance Testing of Shipping Containers and Systems	ASTM D4169-16
Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing	ASTM D4332-14
Standard Test Method for Determining Integrity of Seals for Medical Packaging by Visual Inspection	ASTM F 1886/F 1886M-15
Packaging for terminally sterilized medical devices Part 5: Sealable pouches and reels of porous materials and plastic film construction — Requirements and test methods	BS EN 868-5
Sterilization of healthcare products – Radiation – Part 2: Establishing the sterilization dose	IS/EN/ISO 11137-2
Biocompatibility	ISO 10993-1
Sterilization of Health Care Products-Moist heat-Part 1: Requirements for the Development, Validation and Routine Control of a Sterilization Process for Medical Devices	ISO 17665-1
Sterilization of Health Care Products-Moist heat-Part 2: Guidance on the application of ANSI/AAMI/ISO 17665-1	ANSI/AAMI/ISO TIR17665-2:2009
Designing, testing and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers	AAMI TIR12:2010
Comprehensive guide to steam sterilization and sterility assurance in health care facilities	ANSI/AAMI ST79:2010&A4:2013
Guidance on selecting a microbial challenge and inoculation sites for sterilization validation of medical devices	AAMI TIR39:2009
Pyrogenicity – LAL (Kinetic Turbidimetric Assay Pyrogen Test)	ANSI/AAMI ST72:2011 – Bacterial Endotoxins – Test Methods, Routine Monitoring, and Alternatives to Batch Testing
Device functionality and verification	none

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

Conclusions can be drawn from the testing performed that the PRECICE UNYTE CoCr System is substantially equivalent to the predicate device.