NuVasive Specialized Orthopedics, Inc.
Miriam Cervantes
Regulatory Affairs Specialist
101 Enterprise, Suite 100
Aliso Viejo, California 92656
USA

December 22, 2020

Re: K202348
Trade/Device Name: External Remote Controller ERC 4P
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB, KTT, HWC, HRS
Dated: August 17, 2020
Received: August 18, 2020

Dear Miriam Cervantes:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For Michael Owens
Assistant Director
DHT6A: Division of Joint Arthroplasty Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202348

Device Name
External Remote Controller ERC 4P

Indications for Use *(Describe)*
The Precice® System (inclusive of Precice, Precice Stryde, and Precice Bone Transport) is indicated for limb-lengthening, open and closed fracture fixation, pseudarthrosis, mal-unions, non-unions or bone transport of long bones.

The Precice® Plating System is indicated for limb lengthening, open and closed fracture fixation, pseudoarthrosis, mal-unions and non-unions of long bones in pediatrics and small stature adult patients.

The Precice® Ankle Salvage System is intended for tibio-talo-calcaneal fusions. When used for TTC fusion, the Precice Ankle Salvage System may be used for open and closed fracture fixation, pseudarthrosis, mal-unions, non-unions, or bone transport of long bones adjacent to the fusion site. The device may be used for subsequent limb lengthening once tibio-talo-calcaneal fusion has been achieved.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510 (k) Summary
In accordance with Title 21 of the Code of Federal Regulations, Part 807, and in particular 21 CFR §807.92, the following summary of information is provided:

A. Submitted by:

Miriam Cervantes
Regulatory Affairs Specialist
NuVasive Specialized Orthopedics Incorporated
101 Enterprise, Suite 100
Aliso Viejo, California, 92656
Telephone: (909) 229-7836

Date Prepared: August 17, 2020

B. Device name

Proprietary Name:	External Remote Controller ERC 4P
Common or Usual Name:	Intramedullary Fixation Rod, Smooth or threaded metallic bone fixation fastener
Classification Name:	Rod, Fixation, Intramedullary and Accessories
Regulation Number:	21 CFR § 888.3020, 21 CFR 888.3030, 21 CFR 888.3040
Classification:	Class II
Product Code (primary):	HSB
Product Code (subsequent):	KTT, HWC, HRS

C. Predicate Devices

The subject External Remote Controller ERC 4P is substantially equivalent to the primary predicate device, Precice System (K191336), and additional predicate devices Precice Intramedullary Limb Lengthening System (K113219) Precice Plating System (K192181) and Precice Ankle Salvage System (K200430).

D. Device Description

The fourth generation External Remote Controller ERC 4P is a portable hand-held system used to non-invasively distract or retract the *Precice System Family* implants. The *ERC 4P* device has a touch screen interface, ergonomic design, a single magnet, and implant detection features that provide feedback to the user on the status of the coupling of the implant with the *ERC 4P*. It can be operated either cordlessly through a rechargeable battery or with a power cord. When the *ERC 4P* magnet begins to rotate, it induces a magnetic field which rotates an internal magnet attached to a lead screw in the implanted nail/plate, which then either distracts or retracts accordingly. The *ERC 4P* has a touch screen interface, as well as a hard button for the user's modes of interaction.

The purpose of this 510(k) Premarket Notification is to expand the indications for use of the *ERC 4P* to allow its use with the *Precice Plating System* and the *Precice Ankle Salvage System*.

E. Indications for Use

The Precice® System (inclusive of Precice, Precice Stryde, and Precice Bone Transport) is indicated for limb-lengthening, open and closed fracture fixation, pseudarthrosis, mal-unions, non-unions or bone transport of long bones.

The Precice® Plating System is indicated for limb lengthening, open and closed fracture fixation, pseudoarthrosis, mal-unions and non-unions of long bones in pediatrics and small stature adult patients.

The Precice® Ankle Salvage System is intended for tibio-talo-calcaneal fusions. When used for TTC fusion, the Precice Ankle Salvage System may be used for open and closed fracture fixation, pseudarthrosis, mal-unions, non-unions, or bone transport of long bones adjacent to the fusion site. The device may be used for subsequent limb lengthening once tibio-talo-calcaneal fusion has been achieved.

F. Technological Characteristics

As was established in this submission, the subject External Remote Controller ERC 4P is substantially equivalent to the predicate device cleared by the FDA for commercial distribution in the United States. The subject device was shown to be substantially equivalent and have equivalent technological characteristics to its predicate devices through comparison in areas including design, intended use, material composition, and functions.

G. Performance Data

Nonclinical testing was performed to demonstrate that the subject External Remote Controller ERC 4P is substantially equivalent to predicate devices. Following testing have been included in the submission to show substantial equivalence to the predicate device.

Test	Applicable standard
Electrical Safety	IEC 60601-1
Electromagnetic Compatibility and Interference	IEC 60601-1-2
Magnet Safety Analysis	N/A
Usability Study	N/A
Labeling Readability	N/A

H. Conclusions

Based on the indications for use, technological characteristics, performance testing, and comparison to predicate device, the subject External Remote Controller ERC 4P has been shown to be substantially equivalent to legally marketed predicate device.