May 8, 2020

NuVasive Specialized Orthopedics, Inc.
Madison Heffron
Regulatory Affairs Specialist
101 Enterprise, Suite 100
Aliso Viejo, California 92656

Re: K193617
Trade/Device Name: Precice Screws
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB, KTT, HRS, HWC
Dated: April 7, 2020
Received: April 9, 2020

Dear Madison Heffron:

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,

Shumaya Ali, M.P.H.
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma 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)*
K193617

Device Name

The Precice® Screws

Indications for Use *(Describe)*

The Precice® Screws are provided sterile and intended to be used with the systems below:

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

The *Precice® Stryde System* is indicated for limb lengthening, open and closed fracture fixation, pseudoarthrosis, mal-unions, non-unions, or bone transport of long bones.

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

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

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® Screws
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:

Madison Heffron
Regulatory Affairs Specialist
NuVasive Specialized Orthopedics, Inc.
101 Enterprise, Suite 100
Aliso Viejo, CA 92656
Telephone: (949) 532-7868

Date Prepared: May 7th, 2020

B. Device Name

Trade or Proprietary Name:	*Precice® Screws*
Common or Usual Name:	Screw, Fixation, Bone
Classification Name:	Smooth or threaded metallic bone fixation fastener
Device Class:	Class II
Classification:	21 CFR § 888.3020, 888.3030, and 888.3040
Product Code:	HSB, KTT & HRS, and HWC

C. Predicate Devices

The subject *Precice® Screws* are substantially equivalent to the predicate device the *Precice® System (*K172628*)* and additional predicates, *Precice® Stryde System (*K180503*), Precice® Bone Transport (*K182170*),* and *Precice® Plate System (*K192181*).*

D. Device Description

The *Precice Screws* accompanying previously cleared *Precice System (*K172628*)* and additional predicates, *Precice Stryde System (*K180503*), Precice Bone Transport (*K182170*),* and *Precice Plate System (*K192181) are available in a variety of lengths, materials and thread styles. The screws are offered in lengths between 10-100mm and styles including pegs, partially threaded and fully threaded shaft designs.

The purpose of this submission is to introduce a sterile option of previously cleared screws as part of the *Precice System (*K172628*)* and additional predicates, *Precice Stryde System (*K180503*), Precice Bone Transport (*K182170*),* and *Precice Plate System (*K192181*).*

E. Indications for Use

The *Precice® Screws* are provided sterile and intended to be used with the systems below:

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

The *Precice® Stryde System* is indicated for limb lengthening, open and closed fracture fixation, pseudoarthrosis, mal-unions, non-unions, or bone transport of long bones.

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

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

F. Technological Characteristics

As was established in this submission, the subject *Precice Screws* are substantially equivalent to other predicate devices 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 device through comparison in areas including design, labeling/intended use, material composition, and function.

G. Performance Data

Gamma sterilization validation, sterile packaging validation, and integrity of the sterile barrier over time validation are performed to qualify new packaging and sterilization method for the *Precice Screws*.

The results demonstrate that the subject *Precice Screws* are substantially equivalent to the predicate.

H. Conclusions

The subject *Precice Screws* have been shown to be substantially equivalent to the legally marketed predicate devices.