



June 18, 2026

NuVasive Specialized Orthopedics
Suganya Gopalakrishnan
Regulatory Specialist
2560 General Armistead Ave.
Audubon, Pennsylvania 19403

Re: K261651

Trade/Device Name: Precice™ Max System and Precice™ Ankle Salvage System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB, HWC
Dated: May 18, 2026
Received: May 19, 2026

Dear Suganya Gopalakrishnan:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Joseph P. Russell -S

for: Farzana Sharmin, PhD

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K261651

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Please provide the device trade name(s).

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Precice™ Max System and Precice™ Ankle Salvage System

Please provide your Indications for Use below.

?

Precice™ Max System

The Precice™ Max System is indicated for limb lengthening, open and closed fracture fixation, pseudarthrosis, malunions, nonunions, or bone transport of long bones in patients age 18 years and older and indicated for limb lengthening of the femur and tibia in pediatric patients (greater than 12 years old).

Precice™ Ankle Salvage System

The Precice™ Ankle Salvage System is indicated for tibio-talo-calcaneal fusions in adults. When used for tibio-talo-calcaneal 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.

Please select the types of uses (select one or both, as applicable).

Prescription Use ([21 CFR 801 Subpart D](#))

Over-The-Counter Use ([21 CFR 801 Subpart C](#))

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Please select the age group(s) for which the device(s) is to be used.

Neonates/Newborns (Birth to < 29 days old)

Infants (29 days old to < 2 years old)

Children (2 years old to < 12 years old)

Adolescents (12 years old to < 22 years old)

Adults (22 years old and greater)

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510(k) Summary: Precice™ Max System and Precice™ Ankle Salvage System

Company: NuVasive Specialized Orthopedics
2560 General Armistead Ave.
Audubon, PA 19403
610-930-1800

Primary Contact: Suganya Gopalakrishnan
Regulatory Specialist

Secondary Contact: Jennifer Antonacci, Ph.D.
Director, Regulatory Affairs

Date Prepared: June 16, 2026

Device Name: Precice™ Max System
Precice™ Ankle Salvage System

Common Name: Intermedullary Fixation Rod
Screw, Fixation, Bone

Classification: Per 21 CFR as follows:
§888.3020 Intramedullary fixation rod
§888.3040 Smooth or threaded metallic bone fixation fastener
Product Code: HSB, HWC
Regulatory Class: II, Panel Code: 87

Primary Predicate: Precice™ Intramedullary Limb Lengthening System (K170346)

Additional Predicates: Precice™ Max System (K232267)
Precice™ Ankle Salvage System (K230765)
Precice™ Intramedullary Limb Lengthening System (K220234)

Purpose:

The purpose of this submission is to request clearance for non-sterile locking screws and end caps, that were previously cleared sterile, as an additional option for use with the Precice™ Max System and Precice™ Ankle Salvage System.

Device Description:

Precice™ Max System

The Precice™ Max system is designed to achieve limb correction through gradual lengthening or compression and provide intramedullary fixation for fractures of long bones. The Precice™ Max System includes intramedullary nails, endcaps, locking screws, and surgical instruments, and is compatible with an External Remote Controller (ERC). The Precice™ Max nail is secured to bone with locking screws. The locking screws are available in a variety of diameters, lengths, and thread styles. Implants are manufactured from titanium alloy.

Precice™ Ankle Salvage System

The Precice™ Ankle Salvage System is a tibio-talo-calcaneal fusion system that consists of the Precice™ Ankle Salvage nails, locking screws, end caps, and surgical instruments, and is compatible with an External Remote Controller (ERC). The Precice™ Ankle Salvage nail is secured to bone with locking screws. The locking screws are available in a variety of diameters, lengths, and thread styles. Implants are manufactured from titanium alloy.

Indications for Use:

Precice™ Max System

The Precice™ Max System is indicated for limb lengthening, open and closed fracture fixation, pseudarthrosis, malunions, nonunions, or bone transport of long bones in patients age 18 years and older and indicated for limb lengthening of the femur and tibia in pediatric patients (greater than 12 years old).

Precice™ Ankle Salvage System

The Precice™ Ankle Salvage System is indicated for tibio-talo-calcaneal fusions in adults. When used for tibio-talo-calcaneal fusion, the Precice™ Ankle Salvage System may be used for open and closed fracture fixation, pseudarthrosis, malunions, 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.

Technological Characteristics:

Subject non-sterile locking screws and end caps have the same technological characteristics as the predicate devices including identical design, intended use, material composition, function, and range of sizes. The only difference is that the subject devices are provided non-sterile, whereas the predicate devices are supplied sterile.

Performance Data:

Subject non-sterile locking screws and end caps are adopted within existing steam sterilization validations conducted in accordance with ISO 17665-1. Mechanical

testing was not repeated for the subject non-sterile locking screws and end caps as there are no design changes to the previously cleared sterile implants.

Basis of Substantial Equivalence:

The subject non-sterile locking screws and end caps have been found to be substantially equivalent to the predicate device with respect to technical characteristics, performance, and intended use. The information provided supports substantial equivalence to the predicate device.