PRECICE UNYTE System
510(k) Summary – K172061
August 7, 2017

1. **Company:** NuVasive Specialized Orthopedics, Inc.
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2. **Proprietary Trade Name:** PRECICE UNYTE 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 System is composed of the PRECICE UNYTE Nail (supplied sterile), locking screws, end cap, surgical instruments and an external remote controller (ERC). The Nail is available in various diameters, lengths and screwhole configurations to accommodate a variety of patient anatomies. The locking screws are also available in a variety of diameters and lengths. The PRECICE UNYTE Nail and end cap is supplied sterile by gamma radiation while the locking screws and reusable instruments are supplied non-sterile and must be sterilized prior to use. The UNYTE Nail contains an enclosed rare earth magnet, telescoping lead screw/nut assembly, and planetary gearing. The UNYTE Nail is supplied pre-distracted by 10 mm (femur and tibia models), 15 mm and 20 mm (humeral model), to allow for compression fracture reduction techniques.

6. **Indications:** The PRECICE UNYTE System is indicated for open and closed fracture fixation, corrective osteotomies, pseudoarthrosis, mal-unions and non-unions, limb lengthening, or bone transport of long bones.

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

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

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

Trade Name:	PRECICE Intramedullary Limb Lengthening System
Common Name:	Intramedullary Fixation Rod
510(k) Clearance Number:	K170346

Trade Name:	PRECICE UNYTE CoCr System
Common Name:	Intramedullary Fixation Rod
510(k) Clearance Number:	K162927

Trade Name:	AOS Tibial Nail System
Common Name:	Intramedullary Fixation Rod
510(k) Clearance Number:	K130625

Substantial equivalence is based on indications for use, technological characteristics, and principles of operation.

The PRECICE UNYTE 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 long bones. The PRECICE Intramedullary Limb Lengthening System and PRECICE UNYTE CoCr System reference devices listed above both include limb lengthening with their indications for use. The AOS Tibial Nail System reference device includes bone transport within the indications for use. This 510(k) is intended to expand the indications of the PRECICE UNYTE System to align with the predicate and reference devices in the PRECICE family and in the same product code by including limb lengthening and bone transport.

The PRECICE UNYTE System has the same technological characteristics and the same principle of operation as that of the predicate. The design of both intramedullary nails is identical. Both devices are inserted into the intramedullary canal of the long bone and secured with locking screws. Both devices are adjusted non-invasively by the External Remote Controller (ERC).

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

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 ERC use with the predicate PRECICE UNYTE Nail System for the ERC are applicable.

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