Stryker GmbH
Jackie Perri
Senior Regulatory Affairs Specialist
325 Corporate Drive
MAHWAH, NJ 07430

July 01, 2020

Re: K200880
Trade/Device Name: T2 Tibial Nailing System, T2 Femoral Nail System, T2 Supracondylar Nail System, T2 Recon Nail System, T2 Greater Trochanter Nail (GTN), T2 Ankle Arthrodesis Nail, T2 Arthrodesis Nail System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: April 1, 2020
Received: April 2, 2020

Dear Jackie Perri:

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,

Michael Owens
Acting 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)* K200880

Device Name
T2 Tibial Nailing System

Indications for Use *(Describe)*
The T2 Tibial Nailing System is intended to provide temporary stabilization of various types of fractures, malunions and nonunion of the tibia. The nails are inserted using an opened or closed technique and can be statically, dynamically and compressed locked.

The T2 Tibial Nailing System is indicated for long bone fracture fixation, specifically tibial fracture fixation, which may include the following:

- Open and closed tibial fractures
- Pseudoarthrosis and correction osteotomy
- Pathologic fractures, impending pathologic fractures, and tumor resections
- Nonunion and malunion

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.

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)* K200880

Device Name
T2 Femoral Nail System

Indications for Use *(Describe)*
The T2 Femoral Nail is indicated for long bone fracture fixation specifically femoral fracture fixation which may include the following:

- Open and closed femoral fractures
- Pseudoarthrosis and correction osteotomy
- Pathologic fractures, impending pathologic fractures, and tumor resections
- Supracondylar fractures, including those with intra-articular extension
- Ipsilateral femur fractures
- Fractures proximal to a total knee arthroplasty
- Fractures distal to hip joint
- Nonunions and malunions

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)

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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)* K200880

Device Name
T2 Supracondylar Nail System

Indications for Use *(Describe)*

The T2 Supracondylar Nail System is indicated for:

- Open and closed femoral fractures
- Pseudoarthrosis and correction osteotomy
- Pathologic fractures, impending pathologic fractures, and tumor resections
- Supracondylar fractures including those with intra-articular extension
- Fractures distal to total hip prosthesis
- Nonunions and malunions

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)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)* K200880

Device Name
T2 Recon Nail System

Indications for Use *(Describe)*
The T2 Recon Nail is indicated for:

- Subtrochanteric fractures
- Intertrochanteric fractures
- Ipsilateral neck/shaft fractures
- Comminuted proximal femoral shaft fractures
- Femoral fixation required as a result of pathological disease
- Temporary stabilization of fractures of the femoral shaft – ranging from the femoral neck to the supracondylar regions of the femur.

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)

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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)* K200880

Device Name
T2 Greater Trochanter Nail (GTN)

Indications for Use *(Describe)*
The T2 Greater Trochanter Nail is indicated for long bone fracture fixation, which may include the following:

- Open and closed femoral fractures
- Pseudarthrosis and correction osteotomy
- Pathologic fractures, impending pathologic fractures, and tumor resections
- Ipsilateral femur fractures
- Fractures proximal to a total knee arthroplasty
- Nonunions and malunions.

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)

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FORM FDA 3881 (7/17) PSC Publishing Services (301)

443-6740 EF

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)* K200880

Device Name
T2 Ankle Arthrodesis Nail

Indications for Use *(Describe)*

The T2 Ankle Arthrodesis Nail is intended for tibiotalocalcaneal arthrodesis (fusion) and to provide stabilization of the hindfoot and ankle including the transverse tarsal joints coupling the mid-foot to the hindfoot. Examples of specific indications include:

- Post-traumatic or primary Arthrosis
- Previously infected arthrosis (second degree)
- Revision of Failed Ankle Arthrodesis
- Failed Total Ankle Replacement
- Avascular Necrosis of the Talus (requiring tibiocalcaneal arthrodesis)
- Neuroarthropathy or Neuromuscular Deformity or other neuromuscular disease with severe deformity or instability of the ankle
- Rheumatoid Arthritis with severe deformity such as rheumatoid hindfoot
- Osteoarthritis
- Nonunions or Pseudarthrosis of hindfoot and distal tibia
- Malunited tibial pilon fracture
- Charcot foot
- Severe endstage degenerative arthritis
- Severe defects after tumor resection
- Pantalar arthrodesis

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)

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FORM FDA 3881 (7/17) Page 1 of 1 PSC Publishing Services (301) 443-6740 EF

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)* K200880

Device Name
T2 Arthrodesis Nail System

Indications for Use *(Describe)*

The T2 Arthrodesis Nail is intended for long bone internal fixation, which may include the following:

- Aseptic failed total knee arthroplasty
- Open and closed femoral fractures
- Pseudoarthrosis and correction osteotomy
- Pathological fractures, impending pathological fractures, and tumor resections
- Ipsilateral femur fractures
- Failed external fixation, nonunions and malunions
- Periarticular fractures where repair is not possible
- Knee arthrodesis

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)

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510(k) Summary

Sponsor:

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Contact Person:

Jackie Perri
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325 Corporate Drive
Mahwah, NJ 07430
Phone: (732) 770-5616

Date Prepared:

March 31, 2020

Proprietary Name:

T2 Tibial Nailing System
T2 Femoral Nail System
T2 Supracondylar Nail System
T2 Recon Nail System
T2 Greater Trochanter Nail (GTN)
T2 Ankle Arthrodesis Nail
T2 Arthrodesis Nail System

Common Name:

T2 Tibial Nailing System
Tibial Nail
T2 Femoral Nail System
Intramedullary Nail, Femoral Nail
T2 Supracondylar Nail System
Intramedullary Nail
T2 Recon Nail System
Intramedullary Nail
T2 Greater Trochanter Nail (GTN)
Intramedullary Nail, Femoral Nail
T2 Ankle Arthrodesis Nail
Intramedullary Nail
T2 Arthrodesis Nail System
Intramedullary Nail

Regulation Number/Name:

T2 Tibial Nailing System
21CFR 888.3020 (Intramedullary Fixation Rod)
T2 Femoral Nail System
21CFR 888.3020 (Intramedullary Fixation Rod)
T2 Supracondylar Nail System
21CFR 888.3020 (Intramedullary Fixation Rod)
T2 Recon Nail System
21CFR 888.3020 (Intramedullary Fixation Rod)

T2 Greater Trochanter Nail (GTN)
21CFR 888.3020 (Intramedullary Fixation Rod)
T2 Ankle Arthrodesis Nail
21CFR 888.3020 (Intramedullary Fixation Rod)
T2 Arthrodesis Nail System
21CFR 888.3020 (Intramedullary Fixation Rod)

Product Code:

T2 Tibial Nailing System
HSB (Rod, fixation, intramedullary and accessories)
T2 Femoral Nail System
HSB (Rod, fixation, intramedullary and accessories)
T2 Supracondylar Nail System
HSB (Rod, fixation, intramedullary and accessories)
T2 Recon Nail System
HSB (Rod, fixation, intramedullary and accessories)
T2 Greater Trochanter Nail (GTN)
HSB (Rod, fixation, intramedullary and accessories)
T2 Ankle Arthrodesis Nail
HSB (Rod, fixation, intramedullary and accessories)
T2 Arthrodesis Nail System
HSB (Rod, fixation, intramedullary and accessories)

Device Class: Class II

Predicate Device:

T2 Tibial Nailing System – K003018 and K131365
T2 Femoral Nail System – K081152, K021744 and K010801
Synthes Solid Femoral Nail - K923580
T2 Supracondylar Nail System – K023267
T2 Recon Nail System – K102992 and K032898
T2 Greater Trochanter Nail (GTN) – K101438
T2 Ankle Arthrodesis Nail - K051590
T2 Arthrodesis Nail System – K020384

Description

T2 Tibial Nailing System
The T2 Tibial Nailing System is a cylindrical tube manufactured from titanium alloy and slightly bowed to accommodate the shape of the tibia. Locking screws, compression screws and an end cap are manufactured from titanium alloy and are used with the nails. The T2 Tibial Nailing System is available in three versions, each differing from the other only in diameter, length and number and orientation of screw holes.

T2 Femoral Nail System
The T2 Femoral Nail is a cylindrical, cannulated titanium alloy tube, slightly bowed to accommodate the shape of the femur. The T2 Femoral Nail may be inserted into the femoral canal using either a retrograde or antegrade surgical approach.

T2 Supracondylar Nail System
The T2 Supracondylar Nails are retrograde nails with a one-piece round profiled shaft design. The nails are cannulated and have a closed-section design with proximal rounded end. The T2 Supracondylar Nail is available in two versions: Short and Long. The T2 Supracondylar nails are available in lengths from 170 mm to 440 mm and in diameters from 9 mm to 14 mm. The T2 Supracondylar Nail System offers nails in varying lengths, a combination of locking screws, condyle screws, nuts and end caps.

T2 Recon Nail System
The T2 Recon Nail System is a family of nails for various types of femoral fractures. The system includes Recon Nails in various lengths and diameters (both left and right versions), Lag Screws, Locking Screws, end caps, an Antegrade Set Screw and other accessories for use with the nails.

T2 Greater Trochanter Nail (GTN)
The T2 Greater Trochanter Nail (GTN) is a cylindrical, cannulated titanium alloy tube, slightly bowed to accommodate the shape of the femur. The T2 GTN may be inserted into the femoral canal using either a retrograde or antegrade surgical approach.

T2 Ankle Arthrodesis Nail
The T2 Ankle Arthrodesis Nail is a fluted, cannulated, titanium alloy nail and has a compression screw to provide internal compression of the upper ankle joint. The nail is inserted using an open or closed technique and can be locked in static, dynamic or compression mode. The T2 Ankle Arthrodesis Nail and accessories are intended for single use only. The T2 Ankle Arthrodesis Nail is available in left and right version in diameters 10 mm to 13 mm with the length ranging from 150 mm to 480 mm in increments of either 20mm or 50 mm. It has a 5˚lateral bend.

T2 Arthrodesis Nail System
The T2 Arthrodesis Nails have a one-piece round profiled shaft design. The nails are cannulated and have a closed-section design with distal rounded end. The T2 Arthrodesis Nail is available in lengths from 540 mm to 780 mm in 40 mm increments, and in diameters from 10 mm to 15 mm.

Indications for Use

T2 Tibial Nailing System
The T2 Tibial Nailing System is intended to provide temporary stabilization of various types of fractures, malunions and nonunion of the tibia. The nails are inserted using an opened or closed technique and can be statically, dynamically and compressed locked.

The T2 Tibial Nailing System is indicated for long bone fracture fixation, specifically tibial fracture fixation, which may include the following:

- Open and closed tibial fractures
- Pseudoarthrosis and correction osteotomy
- Pathologic fractures, impending pathologic fractures, and tumor resections
- Nonunion and malunion

T2 Femoral Nail System

The T2 Femoral Nail is indicated for long bone fracture fixation specifically femoral fracture fixation, which may include the following:

- Open and closed femoral fractures
- Pseudoarthrosis and correction osteotomy
- Pathologic fractures, impending pathologic fractures, and tumor restrictions
- Supracondylar fractures, including those with intra-articular extension
- Ipsilateral femur fractures
- Fractures proximal to a total knee arthroplasty
- Fractures distal to hip joint
- Nonunions and malunions

T2 Supracondylar Nail System

The T2 Supracondylar Nail System is indicated for:

- Open and closed femoral fractures
- Pseudoarthrosis and correction osteotomy
- Pathologic fractures, impending pathologic fractures, and tumor resections
- Supracondylar fractures including those with intra-articular extension
- Fractures distal to total hip prosthesis
- Nonunions and malunions

T2 Recon Nail System

The T2 Recon Nail is indicated for:

- Subtrochanteric fractures
- Intertrochanteric fractures
- Ipsilateral neck/shaft fractures
- Comminuted proximal femoral shaft fractures
- Femoral fixation required as a result of pathological disease
- Temporary stabilization of fractures of the femoral shaft – ranging from the femoral neck to the supracondylar regions of the femur.

T2 Greater Trochanter Nail (GTN)

The T2 Greater Trochanter Nail is indicated for long bone fracture fixation, which may include the following:

- Open and closed femoral fractures
- Pseudarthrosis and correction osteotomy
- Pathologic fractures, impending pathologic fractures, and tumor resections
- Ipsilateral femur fractures
- Fractures proximal to a total knee arthroplasty
- Nonunions and malunions.

T2 Ankle Arthrodesis Nail

The T2 Ankle Arthrodesis Nail is intended for tibiotalocalcaneal arthrodesis (fusion) and to provide stabilization of the hindfoot and ankle including the transverse tarsal joints coupling the mid-foot to the hindfoot. Examples of specific indications include:

- Post-traumatic or primary Arthrosis
- Previously infected arthrosis (second degree)
- Revision of Failed Ankle Arthrodesis
- Failed Total Ankle Replacement
- Avascular Necrosis of the Talus (requiring tibiocalcaneal arthrodesis)
- Neuroarthropathy or Neuromuscular Deformity or other neuromuscular disease with severe deformity or instability of the ankle
- Rheumatoid Arthritis with severe deformity such as rheumatoid hindfoot
- Osteoarthritis
- Nonunions or Pseudarthrosis of hindfoot and distal tibia
- Malunited tibial pilon fracture
- Charcot foot
- Severe endstage degenerative arthritis
- Severe defects after tumor resection
- Pantalar arthrodesis

T2 Arthrodesis Nail System

The T2 Arthrodesis Nail is indicated for long bone internal fixation, which may include the following:

- Aseptic failed total knee arthroplasty
- Open and closed femoral fractures
- Pseudoarthrosis and correction osteotomy
- Pathologic fractures, impending pathologic fractures, and tumor resections
- Ipsilateral femur fractures
- Failed external fixation, nonunions and malunions
- Periarticular fractures where repair is not possible
- Knee arthrodesis

Summary of Technologies

The purpose of this 510(k) is to gain clearance to market T2 Nails cleared in the systems listed below as compatible with the Locking Screws of the IMN Screws System, previously cleared in K172774, and the IMN Instrumentation.

A comparison of the systems demonstrated that the subject T2 Tibial Nailing System is substantially equivalent to the predicate T2 Tibial Nailing System (K003018 and K131365) regarding intended use, material, design and operational principals.

A comparison of the systems demonstrated that the subject T2 Femoral Nailing System is substantially equivalent to the predicate T2 Femoral Nailing System (K081152, K021744 and K010801) and Synthes Solid Femoral Nail (K923580) regarding intended use, material, design and operational principals.

A comparison of the systems demonstrated that the subject T2 Supracondylar Nail System is substantially equivalent to the predicate T2 Supracondylar Nail System (K023267) regarding intended use, material, design and operational principals.

A comparison of the systems demonstrated that the subject T2 Recon Nail System is substantially equivalent to the predicate T2 Recon Nail System (K102992 and K032898) regarding intended use, material, design and operational principals.

A comparison of the systems demonstrated that the subject T2 Greater Trochanter Nail System (GTN) is substantially equivalent to the predicate T2 Greater Trochanter Nail System (GTN) (K101438) regarding intended use, material, design and operational principals.

A comparison of the systems demonstrated that the subject T2 Ankle Arthrodesis Nail System is substantially equivalent to the predicate T2 Ankle Arthrodesis Nail System (K051590) regarding intended use, material, design and operational principals.

A comparison of the systems demonstrated that the subject T2 Arthrodesis Nail System is substantially equivalent to the predicate T2 Arthrodesis Nail System (K020384) regarding intended use, material, design and operational principals.

Non-Clinical Testing

The Locking Screws (05mm, 25mm - 120mm length) of the IMN Screws System (IMN LS, recently cleared in K172774) were developed for locking of the T2 Alpha nails (recently cleared in K172774 and K180436). Further, compatibility of the IMN LS was proven to the existing T2 nails formerly cleared in:

- K003018 and K131365 [T2 Tibial Nailing System]
- K081152, K021744 and K010801 [T2 Femoral Nail System]
- K023267 [T2 Supracondylar Nail System]
- K102992 and K032898 [T2 Recon Nail System]
- K101438 [T2 Greater Trochanter Nail (GTN)]
- K051590 [T2 Ankle Arthrodesis Nail]
- K020384 [T2 Arthrodesis Nail System]

In a computational assessment, constructs of T2 nails and IMN Locking Screws were compared to constructs of T2 nails used with T2 Locking Screw, Fully Threaded (T2 Locking Screw, formerly cleared in K003018) as defined in the respective operative techniques.

The interface compatibility of the IMN Locking Screws (Ø 5 mm) with all T2 nails was shown in IMN Screws DQF 25-039 Functional Interface Analysis-Locking Screws. The performance of the IMN Locking Screw (Ø5 mm) was shown to be equal or higher than the performance of the T2 Locking

Screw (Ø5 mm) in various test disciplines. If the same nail is used in a construct test with IMN Locking Screw (Ø5 mm) and T2 Locking Screw (Ø5 mm), the IMN Locking Screw construct will provide an equal or higher performance. Based on this, equal or higher construct strength of the IMN Locking Screw (Ø5 mm) in combination with the T2 nails is ensured and all acceptance criteria were fulfilled.

Updated Report data for the previously cleared T2 Femoral Nail System

Following reevaluation of the dynamic fatigue strength testing of the T2 Femoral Nails, new Student t-tests were performed with the corrected data input. An additional predicate device was identified, the 09mm Synthes Solid Femoral Nail (K923580), which was tested in the same manner and statistically compared to the T2 Femoral Nails. The T2 Femoral Nail System was shown to be substantially equivalent to the additional predicate regarding intended use, material, design and operational principals.

Clinical Testing

Clinical testing was not required for this submission.

Conclusion

The subject T2 Tibial Nailing System , T2 Femoral Nail System, T2 Supracondylar Nail System, T2 Recon Nail System, T2 Greater Trochanter Nail (GTN), T2 Ankle Arthrodesis Nail, and T2 Arthrodesis Nail System are substantially equivalent to the predicate T2 Tibial Nailing System , T2 Femoral Nail System, T2 Supracondylar Nail System, T2 Recon Nail System, T2 Greater Trochanter Nail GTN), T2 Ankle Arthrodesis Nail, and T2 Arthrodesis Nail System.