



Stryker GmbH
Jemin Dedania
Associate Manager Regulatory Affairs
325 Corporate Drive
Mahwah, New Jersey 07430

February 26, 2021

Re: K203819

Trade/Device Name: T2 Alpha Femur Retrograde Nailing System, T2 Alpha Femur Antegrade GT/PF Nailing System, T2 Tibial Nailing System, T2 Femoral System, T2 Supracondylar Nail System

Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: December 28, 2020
Received: December 29, 2020

Dear Jemin Dedania:

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

Indications for Use

510(k) Number (if known)

K203819

Device Name

T2 Alpha Femur Retrograde Nailing System

Indications for Use (Describe)

The indications for use of this internal fixation device include:

- 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 involving osteopenic and osteoporotic bone
- Fractures distal to a total hip prosthesis
- Periprosthetic fractures
- 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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Indications for Use

510(k) Number (if known)

K203819

Device Name

T2 Alpha Femur Antegrade GT/PF Nailing System

Indications for Use (Describe)

The indications for use of these internal fixation devices include:

- Fixation of subtrochanteric, intertrochanteric, ipsilateral neck/shaft, 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
- Open and closed femoral fractures
- Pseudoarthrosis and correction osteotomy
- Pathologic fractures, impending pathologic fractures and tumor resections
- Ipsilateral femur fractures
- Fractures proximal to a total knee arthroplasty
- Nonunions and malunions
- Fractures involving osteopenic and osteoporotic bone

The Compression Screw Femur may also be used in conjunction with the T2 Alpha Femur Retrograde System.

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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Indications for Use

510(k) Number (if known)

K203819

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

The Locking Screws may also be used in conjunction with the T2 Alpha Systems.

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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Indications for Use

510(k) Number (if known)

K203819

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

The Condyle Nut and Condyle Screws may also be used in conjunction with the T2 Alpha Femur Retrograde System.

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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Indications for Use

510(k) Number (if known)

K203819

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 a total hip prosthesis
- Nonunions and malunions

The End Cap may also be used in conjunction with the T2 Alpha Femur Retrograde System.

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

I. SUBMITTER

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Date Prepared: February 23, 2021

II. DEVICE

Name of Device: T2 Alpha Femur Retrograde Nailing System
T2 Alpha Femur Antegrade GT/PF Nailing System
T2 Tibial Nailing System
T2 Femoral Nail System
T2 Supracondylar Nail System

Common Name: T2 Alpha Femur Retrograde Nailing System
Rod, fixation, intramedullary and accessories
T2 Alpha Femur Antegrade GT/PF Nailing System
Rod, fixation, intramedullary and accessories
T2 Tibial Nailing System
Tibial Nail
T2 Femoral Nail System
Intramedullary Nail, Femoral Nail
T2 Supracondylar Nail System
Intramedullary Nail

Regulation Number / Name: T2 Alpha Femur Retrograde Nailing System
 21CFR 888.3020 (Intramedullary fixation rod)
T2 Alpha Femur Antegrade GT/PF Nailing System
 21CFR 888.3020 (Intramedullary fixation rod)
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)

Product Code: T2 Alpha Femur Retrograde Nailing System
 HSB (Rod, fixation, intramedullary and accessories)
T2 Alpha Femur Antegrade GT/PF Nailing System
 HSB (Rod, fixation, intramedullary and accessories)
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)

Regulatory Class: Class II

III. PREDICATE DEVICE

Primary Predicate: T2 Supracondylar Nail System (K200880)

Additional Predicates: T2 Femoral Nail (K200880)
 Zimmer Natural Nail System Retrograde
 Femoral Nails (K101622)
 T2 GTN (K200880)
 T2 Tibial Nailing System (K200880)
 T2 Alpha Femur Antegrade GT/PF Nailing System
 (K191271)

IV. DEVICE DESCRIPTION

This Traditional 510(k) submission is being supplied to the U.S. FDA to gain clearance to market the T2 Alpha Femur Retrograde Nailing System and update the Indications for Use for T2 Alpha Femur Antegrade GT/PF Nailing System, T2 Tibial Nailing System, T2 Femoral Nail System, and T2 Supracondylar Nail System to include the compatibility of components with the T2 Alpha Femur Retrograde Nailing System.

This submission encompasses multiple systems (T2 Alpha Femur Retrograde Nailing System, T2 Alpha Femur Antegrade GT/PF Nailing System, T2 Tibial Nailing System, T2 Femoral Nail System, and T2 Supracondylar Nail System) that have similar intended use and will be used together during the surgical procedure.

The T2 Alpha Femur Retrograde Nailing System is a fracture fixation system and includes sterile implants (intramedullary nails in various diameter and sizes, compression screw, and end caps) as well as non-sterile instruments (targeting devices). The femoral nails, compression screw and end caps are made of titanium alloy (Ti6Al4V ELI) as per ASTM F136.

Additionally, the T2 Alpha Femur Retrograde Nailing System will be used with the existing locking screws most recently cleared in K200880 (Titan Tibial Nailing System), the locking screws and advanced locking screws of IMN Screws System (K191271), the condyle screws and nuts most recently cleared in K200880 (T2 Femoral Nail System), the Compression Screw Femur most recently cleared in K191271 (T2 Alpha Antegrade GT/PF Nailing System), and the end caps most recently cleared in K200880 (T2 Supracondylar Nail System), The T2 Alpha Femur Retrograde Nailing System is intended for use with IMN Screws System and IMN Instruments System.

T2 Alpha Femur Antegrade GT/PF Nailing System

The T2 Alpha Femur Antegrade GT/PF Nailing System most recently cleared in K191271 is a fracture fixation system and includes sterile implants (femoral nails in various diameter and sizes, compression screw femur, set screws and end caps) as well as non-sterile instruments (targeting devices).

The sterile implants (Femoral Nail GT, Femoral Nail PF, Compression Screw Femur, and End Cap GT/PF, Set Screws) are made of titanium alloy (Ti6Al4V ELI) per ASTM F136. The set screws are manufactured from titanium alloy (Ti6Al4V ELI) per ASTM F136 and PEEK. The targeting devices are manufactured from stainless steel, PEEK unreinforced as well as PEEK with 30% and 50% carbon fibers.

The T2 Alpha Femur Antegrade GT/PF Nailing System will be used with the locking screws most recently cleared in K200880 (Titan Tibial Nail) that have subsequently also received clearance for use in locking femoral nailing systems (K200880), the Lag Screw Recon of T2 Recon System (K200880), the End Cap Lower Extremity and the Nail Holding Screw Tibia / Femur PF of T2 Alpha Tibia Nailing System (K191271), the locking screws and advanced locking screws of IMN Screws System (K191271), the distal targeting device femur antegrade of IMN Instruments System (K191271) as well as the surgical instruments of IMN Instruments System and T2 Instruments System (510(k) exempt devices).

T2 Tibia Nailing System

The T2 Tibial Locking Nail is a cylindrical tube manufactured from titanium alloy and slightly bowed to accommodate the shape of the tibia. Locking screws, compression screws and various end caps are manufactured from titanium alloy and are used with the nails. The T2 Tibial Locking Nail is available in two 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.

V. INTENDED USE

T2 Alpha Femur Retrograde Nailing System

The T2 Alpha Femur Retrograde Nailing System is intended for temporary stabilization of bone segments or fragments until bone consolidation has been achieved.

T2 Alpha Femur Antegrade GT/PF Nailing System

The T2 Alpha Femur Antegrade GT/PF Nailing System is intended for temporary stabilization of bone segments or fragments until bone consolidation has been achieved.

T2 Tibial Nailing System

The T2 Tibial Locking Nail 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.

T2 Femoral Nail System

The T2 Femoral Nail System is intended to provide strong and stable internal fixation with minimal soft tissue irritation. This device is utilized as an aid to healing, not as a substitute for normal intact bone and tissue.

T2 Supracondylar Nail System

The T2 Supracondylar Nail System is intended to provide strong and stable internal fixation with minimal soft tissue irritation. This device is utilized as an aid to healing, not as a substitute for normal intact bone and tissue.

VI. INDICATION FOR USE

T2 Alpha Femur Retrograde Nailing System

The indications for use of this internal fixation device include:

- 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 involving osteopenic and osteoporotic bone
- Fractures distal to a total hip prosthesis
- Periprosthetic fractures
- Nonunions and malunions

T2 Alpha Femur Antegrade GT/PF Nailing System

The indications for use of these internal fixation devices include:

- Fixation of subtrochanteric, intertrochanteric, ipsilateral neck/shaft, 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
- Open and closed femoral fractures
- Pseudoarthrosis and correction osteotomy
- Pathologic fractures, impending pathologic fractures and tumor resections
- Ipsilateral femur fractures
- Fractures proximal to a total knee arthroplasty
- Nonunions and malunions
- Fractures involving osteopenic and osteoporotic bone

The Compression Screw Femur may also be used in conjunction with the T2 Alpha Femur Retrograde System.

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

The Locking Screws may also be used in conjunction with the T2 Alpha Systems.

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 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

The Condyle Nut and Condyle Screws may also be used in conjunction with the T2 Alpha Femur Retrograde System.

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

The End Cap may also be used in conjunction with the T2 Alpha Femur Retrograde System.

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Device comparison demonstrated that the T2 Alpha Femur Retrograde Nailing System, is substantially equivalent to the existing nails of the T2 Supracondylar Nail System (K200880), the

T2 Femoral Nail (K200880), and the Zimmer Natural Nail System Retrograde Femoral Nails (K101622). The subject device and the predicate devices have the same intended use, indications for use, technological characteristics (design features, material and performance) as well as operating principle. At a high level, the subject device and predicate devices have the same technological characteristics, which include:

- Intramedullary nailing systems to provide a fracture fixation of the femur,
- Nail and screw design (length, diameter, and shape), and
- Nails, compression screw and end caps manufactured from titanium alloy (Ti6Al4V ELI) per ASTM F136.
- Hole configurations in proximal and distal part of nail, and
- Locking configurations.

VIII. PERFORMANCE DATA

The following performance data was provided in support of the substantial equivalence determination.

Comparative mechanical testing to the predicate systems demonstrated substantial equivalence.

The following tests were performed:

- Testing of mechanical properties per ASTM F1264 (static stiffness, static strength, and dynamic fatigue strength)
- Fatigue strength testing
- Cut-out testing
- Targeting accuracy testing (targeting stiffness testing)

Mechanical testing demonstrated that the T2 Alpha Femur Retrograde Nailing System is equivalent to the predicate devices (K200880, K101622).

MR assessments of magnetically-induced displacement force, magnetically-induced torque, RF-induced heating, and image artifacts demonstrate that the T2 Alpha Femur Retrograde Nailing System is MR conditional (ASTM F2052 for magnetically induced displacement force, ASTM F2213 for magnetically induced torque, ASTM F2182 for RF heating, and ASTM F2119 for image artifacts).

The Bacterial Endotoxin Testing demonstrated that the sterile implants of T2 Alpha Femur Retrograde Nailing System meet the specified endotoxin limit.

IX. CLINICAL TESTING

No clinical testing of the T2 Alpha Femur Retrograde Nailing System has been conducted.

X. CONCLUSIONT2 Alpha Femur Retrograde Nailing System

The T2 Alpha Femur Retrograde Nailing System is substantially equivalent to the previously cleared T2 Supracondylar Nail System (K200880) primary predicate system and the T2 Femoral Nail (K200880), T2 GTN (K200880), and the Zimmer Natural Nail System Retrograde Femoral Nails (K101622) additional predicates.

T2 Supracondylar Nail System, T2 Femoral Nail System, and T2 Tibial Nailing System

The subject T2 Supracondylar Nail System, T2 Femoral Nail System, and T2 Tibial Nailing System are substantially equivalent to the predicate T2 Supracondylar Nail System, T2 Femoral Nail System, and T2 Tibial Nailing System (K200880) identified in this premarket notification.

T2 Alpha Femur Antegrade GT/PF Nailing System

The T2 Alpha Femur Antegrade GT/PF Nailing System is substantially equivalent to the predicate device (T2 Alpha Femur Antegrade GT/PF Nailing System (K191271)) identified in this premarket notification.