June 6, 2018

Stryker Trauma GmbH
Heike Gustke
Staff Regulatory Affairs Specialist
Prof-Kuentscher-Str. 1-5
Schoenkirchen, 24232 De

Re: K180436
Trade/Device Name: T2 Alpha Tibia Nailing System, T2 Alpha Femur Antegrade GT/PF Nailing System, IMN Screws System, IMN Instruments System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB, HWC
Dated: April 30, 2018
Received: May 4, 2018

Dear Dr. Gustke:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Vincent J. Devlin -S

for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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)*
K180436

Device Name
T2 Alpha Tibia Nailing System

Indications for Use *(Describe)*
The indications for use of this internal fixation device include:
- Open and closed tibial fractures
- Pseudoarthrosis and correction osteotomy
- Pathologic fractures, impending pathologic fractures, and tumor resections
- Fractures involving osteopenic and osteoporotic bone
- Nonunion and malunion

The End Cap Lower Extremity and the Nail Holding Screw Tibia / Femur PF may also be used in conjunction with the T2 Alpha Femur Antegrade GT/PF Nailing 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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)*

K180436

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

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)*

K180436

Device Name
IMN Screws System

Indications for Use *(Describe)*
The IMN Screws System is intended to stabilize the intramedullary nail-bone construct for temporary stabilization.

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)*

K180436

Device Name
IMN Instruments System

Indications for Use *(Describe)*
The IMN Instruments System is intended to enable the implantation and extraction of intramedullary nail and screw.

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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Section 9: 510(k) Summary

I. SUBMITTER

Sponsor: Stryker Trauma GmbH
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Date Prepared: February 5, 2018

II. DEVICE

Name of Device: T2 Alpha Tibia Nailing System
T2 Alpha Femur Antegrade GT/PF Nailing System
IMN Screws System
IMN Instruments System

Common Name: T2 Alpha Tibia Nailing System
Rod, fixation, intramedullary and accessories
T2 Alpha Femur Antegrade GT/PF Nailing System
Rod, fixation, intramedullary and accessories
IMN Screws System
Screw, fixation, bone
IMN Instruments System
Rod, fixation, intramedullary and accessories

Regulation Number / Name:	T2 Alpha Tibia Nailing System 21CFR 888.3020 (Intramedullary fixation rod) T2 Alpha Femur Antegrade GT/PF Nailing System 21CFR 888.3020 (Intramedullary fixation rod) IMN Screws System 21CFR 888.3040 (Smooth or threaded metallic bone fixation fastener) IMN Instruments System 21CFR 888.3020 (Intramedullary fixation rod)
Product Code:	T2 Alpha Tibia Nailing System HSB (Rod, fixation, intramedullary and accessories) T2 Alpha Femur Antegrade GT/PF Nailing System HSB (Rod, fixation, intramedullary and accessories) IMN Screws System HWC (Screw, fixation, bone) IMN Instruments System HSB (Rod, fixation, intramedullary and accessories)
Regulatory Class:	Class II

III. PREDICATE DEVICE

T2 Alpha Tibia Nailing System

Primary predicate device:	Titan Tibial Nail (K003018)
Additional predicate devices:	Zimmer Natural Nail System Tibial Nail (K082770) Synthes (USA) Tibial Nail System EX (K040762)

IMN Screws System

Predicate device:	IMN Screws System (K172774)
Reference device:	Titan Tibial Nail (K003018)

IMN Instruments System

Predicate device: IMN Instruments System (K172774)

T2 Alpha Femur Antegrade GT/PF Nailing System

Predicate device: T2 Alpha Femur Antegrade GT/PF Nailing System (K172774)

IV. DEVICE DESCRIPTION

A Traditional 510(k) submission is being supplied to the U.S. FDA to gain clearance to market:

- The T2 Alpha Tibia Nailing System,
- Line extension of IMN Screws System (addition of advanced locking screws),
- Line extension of IMN Instruments System (addition of surgical instruments),
- Compatibility of T2 Alpha Femur Antegrade GT/PF Nailing System with IMN Screws System as well as IMN Instruments System, and devices of T2 Alpha Tibia Nailing System

The intended use and indications for use of existing T2 Alpha Femur Antegrade GT/PF Nailing System, IMN Screws System and IMN Instruments System previously cleared in K172774 remain unchanged.

This submission encompasses multiple systems (T2 Alpha Tibia Nailing System, T2 Alpha Femur Antegrade GT/PF Nailing System, IMN Screws System and IMN Instruments System) that have similar intended use and will be used together during the surgical procedure.

T2 Alpha Tibia Nailing System

The T2 Alpha Tibia Nailing System is a fracture fixation system and includes sterile implants (intramedullary nails in various diameter, compression screw and end caps) as well as non-sterile instruments (targeting devices). The sterile implants are made of titanium alloy (Ti6Al4V ELI) as per ASTM F136. The T2 Alpha Tibia Nailing System will be used with the locking screws cleared in K003018 (Titan Tibial Nail) and K172774 (IMN Screws System). Further, End Cap Lower Extremity and the Nail Holding Screw Tibia / Femur PF of T2 Alpha Tibia Nailing System can be used with T2 Alpha Femur Antegrade GT/PF Nailing System (K172774). The T2 Alpha Tibia Nailing System will be used with the existing instruments previously cleared in

K131365 (T2 Tibial Nailing System) and 510(k) exempt devices. The T2 Alpha Tibia Nailing System is intended for use with IMN Screws System and IMN Instruments System.

IMN Screws System

The IMN Screws System includes bone screws (locking screws previously cleared in K172774 and advanced locking screws) that are inserted through the intramedullary nail to stabilize the nail-bone construct. The screws are made of titanium alloy (Ti6Al4V ELI) as per ASTM F136. The IMN Screws System is intended for use with T2 Alpha Tibia Nailing System, T2 Alpha Femur Antegrade GT/PF Nailing System and IMN Instruments System.

IMN Instruments System

The IMN Instruments System includes distal targeting device femur antegrade previously cleared in K172774 as well as surgical instruments that support the implantation and extraction of intramedullary nails and screws. The IMN Instruments System is intended for use with T2 Alpha Tibia Nailing System, T2 Alpha Femur Antegrade GT/PF Nailing System and IMN Screws System.

T2 Alpha Femur Antegrade GT/PF Nailing System

The T2 Alpha Femur Antegrade GT/PF Nailing System previously cleared in K172774 is a fracture fixation system and includes sterile implants (femoral nails in various diameter and sizes, compression screw, set screws and end caps) as well as non-sterile instruments.

The T2 Alpha Femur Antegrade GT/PF Nailing System will be used with the locking screws originally cleared in K003018 (Titan Tibial Nail) that have subsequently also received clearance for use in locking femoral nailing systems (K010801, T2 Femoral Nail System) as well as locking screws previously cleared in K172774 (IMN Screws System) and the T2 Lag Screw Recon previously cleared in K032898 (T2 Recon Nail System). Further, it will be used with the existing instruments previously cleared in K172774 (IMN Instruments System) and 510(k) exempt devices. The T2 Alpha Femur Antegrade GT/PF Nailing System is intended for use with IMN Screws System and IMN Instruments System.

V. INTENDED USE

T2 Alpha Tibia Nailing System

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

IMN Screws System

The IMN Screws System is intended to stabilize the intramedullary nail-bone construct for temporary stabilization.

IMN Instruments System

The IMN Instruments System is intended to enable the implantation and extraction of intramedullary nail and screw.

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.

VI. INDICATION FOR USE

T2 Alpha Tibia Nailing System

The indications for use of this internal fixation device include:

- Open and closed tibial fractures
- Pseudoarthrosis and correction osteotomy
- Pathologic fractures, impending pathologic fractures, and tumor resections
- Fractures involving osteopenic and osteoporotic bone
- Nonunion and malunion

The End Cap Lower Extremity and the Nail Holding Screw Tibia / Femur PF may also be used in conjunction with the T2 Alpha Femur Antegrade GT/PF Nailing System.

IMN Screws System

The IMN Screws System is intended to stabilize the intramedullary nail-bone construct for temporary stabilization.

IMN Instruments System

The IMN Instruments System is intended to enable the implantation and extraction of intramedullary nail and screw.

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

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

T2 Alpha Tibia Nailing System

Device comparison demonstrated that the T2 Alpha Tibia Nailing System is substantially equivalent to the previously cleared Titan Tibial Nail (K003018), Zimmer Natural Nail System Tibial Nail (K082770) and Synthes (USA) Tibial Nail System EX (K040762) in regards to 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 are based on the following same technological elements:

- Intramedullary nailing systems to provide a fracture fixation of the tibia,
- Nail and screw design (length, diameter, and shape), and

- Nails, compression screw and end caps manufactured from titanium alloy (Ti6Al4V ELI) as per ASTM F136.

The following technological difference exists between the subject and predicate devices:

- Hole configurations in proximal and distal part of nail.

The difference has been addressed through performance testing which demonstrates that the subject device is as safe and effective as the predicate devices.

IMN Screws System

Device comparison demonstrated that the IMN Screws System is substantially equivalent to the previously cleared IMN Screws System (K172774) in regards to intended use, indications for use, technological characteristics (material and performance) as well as operating principle. The reference device (Titan Tibial Nail System, K003018) is suitable to provide technical information to help address the safety and effectiveness of a new technological characteristic. At a high level, the subject device and predicate device are based on the following same technological elements:

- Stabilization of intramedullary nail-bone construct,
- Used for proximally and distally locking of nail-bone construct,
- Design (length and diameter), and
- Manufactured from titanium alloy (Ti6Al4V ELI) as per ASTM F136.

The following technological difference exists between the subject and predicate devices:

- Thread design

The difference has been addressed through performance testing which demonstrates that the subject device is as safe and effective as the predicate devices.

IMN Instruments System

Device comparison demonstrated that the IMN Instruments System is substantially equivalent to the previously cleared IMN Instruments System (K172774) in regards to intended use, indications for use, technological characteristics as well as operating principle.

At a high level, the subject device and predicate devices are based on the following same technological elements:

- Used for the implantation and extraction of intramedullary nail and screw, and
- Compatibility with T2 Alpha nailing systems and IMN Screws System.

T2 Alpha Femur Antegrade GT/PF Nailing System

Device comparison demonstrated that the T2 Alpha Femur Antegrade GT/PF Nailing System is substantially equivalent to the previously cleared T2 Alpha Femur Antegrade GT/PF Nailing System (K172774) in regards to intended use, technological characteristics (design features, material and performance) as well as operating principle.

At a high level, the subject device and predicate devices are based on the following same technological elements:

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

VIII. PERFORMANCE DATA

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

T2 Alpha Tibia Nailing System

Non-clinical testing was performed for T2 Alpha Tibia Nailing System under worst case scenario to determine substantial equivalence. The following bench testing was conducted:

- Testing of mechanical properties per ASTM F1264
- Fatigue strength testing (proximal and distal)
- Cut-out testing
- Targeting accuracy testing

Testing demonstrated that T2 Alpha Tibia Nailing System is equivalent in mechanical performance to the predicate devices (K003018, K082770, and K040762).

Non-clinical testing has demonstrated that T2 Alpha Tibia Nailing System is MR Conditional.

Biocompatibility testing (ISO 10993-1, ISO 10993-5 and ISO 10993-18) was performed to evaluate the biological safety of T2 Alpha Tibia Nailing System according to FDA Guidance

'Use of International Standard ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process'. Testing demonstrated that T2 Alpha Tibia Nailing System is biocompatible.

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

IMN Screws System

Non-clinical testing was performed for the advanced locking screws of IMN Screws System. The following bench testing was conducted:

- Testing of mechanical properties as per ASTM F543

Testing demonstrated that the advanced locking screws are equivalent in mechanical performance to the predicate device (K172774) and reference device (K003018).

Non-clinical testing has demonstrated that the advanced locking screws are MR Conditional.

Biocompatibility assessment (ISO 10993-1) was performed according to FDA Guidance 'Use of International Standard ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process'. It has been demonstrated that the advanced locking screws are biocompatible. The Bacterial Endotoxin Testing demonstrated that the advanced locking screws meet the specified endotoxin limit.

IMN Instruments System

Non-clinical testing was performed for the surgical instruments of IMN Instruments System. The following bench testing was conducted:

- Performance testing in cadaver lab, and
- Compatibility evaluation

Testing demonstrated that the surgical instruments are equivalent in performance to the predicate device (K172774).

Biocompatibility testing (ISO 10993-1, ISO 10993-5, and ISO 10993-18) was performed according to FDA Guidance 'Use of International Standard ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process'. It has been demonstrated that the surgical instruments are biocompatible.

T2 Alpha Femur Antegrade GT/PF Nailing System

Non-clinical testing was performed for T2 Alpha Femur Antegrade GT/PF Nailing System to determine substantial equivalence. Compatibility assessment demonstrated that T2 Alpha Femur Antegrade GT/PF Nailing System is suitable to be used with the advanced locking screws of IMN Screws System and the surgical instruments of IMN Instruments System as well as the End Cap Lower Extremity and the Nail Holding Screw Tibia / Femur PF of T2 Alpha Tibia Nailing System.

IX. CLINICAL TESTING

T2 Alpha Tibia Nailing System

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

IMN Screws System

No clinical testing of the IMN Screws System has been conducted.

IMN Instruments System

No clinical testing of the IMN Instruments System has been conducted.

T2 Alpha Femur Antegrade GT/PF Nailing System

No clinical testing of the T2 Alpha Femur Antegrade GT/PF Nailing System has been conducted.

X. CONCLUSION

T2 Alpha Tibia Nailing System

The T2 Alpha Tibia Nailing System is substantially equivalent to the predicate devices (Titan Tibial Nail (K003018), Zimmer Natural Nail System Tibial Nail (K082770), and Synthes (USA) Tibial Nail System EX (K040762)) identified in this premarket notification.

IMN Screws System

The IMN Screws System is substantially equivalent to the predicate device (IMN Screws System (K172774) identified in this premarket notification.

IMN Instruments System

The IMN Instruments System is substantially equivalent to the predicate device (IMN Instruments System (K172774)) 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 (K172774)) identified in this premarket notification.