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

January 12, 2018

Re: K172774
Trade/Device Name: 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: December 8, 2017
Received: December 12, 2017

Dear Heike 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Mark N. Melkerson -S

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)*
K172774

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Section 9: 510(k) Summary

I. SUBMITTER

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Date Prepared: November 30, 2017

II. DEVICE

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

Common Name: 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 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 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 Femur Antegrade GT/PF Nailing System

Primary predicate:	T2 Recon Nail System (K102992)
Additional predicate:	T2 Greater Trochanter Nail (GTN) (K101438) Zimmer Natural Nail System Piriformis Fossa and Greater Trochanter Antegrade Femoral Nails (K083497)

IMN Screws System

Primary predicate:	Titan Tibial Nail (K003018)

IMN Instruments System

Primary predicate:	Gamma3 and T2 Recon Target Devices (K123401)
Reference device:	T2 Recon Nail System (K102992)

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 Antegrade GT/PF Nailing System, IMN Screws System, and IMN

Instruments System. This submission encompasses multiple systems that have similar intended use and will be used together during the surgical procedure.

T2 Alpha Femur Antegrade GT/PF Nailing System

The T2 Alpha Femur Antegrade GT/PF Nailing System is a fracture fixation system and includes sterile implants (intramedullary nails in various diameter and sizes, compression screw, set screws 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. The set screws are manufactured from titanium alloy (Ti6Al4V ELI) as per ASTM F136 and PEEK.

Additionally, the T2 Alpha Femur Antegrade GT/PF Nailing System will be used with the existing locking screws previously cleared in K003018 (Titan Tibial Nail System), the T2 Lag Screw Recon previously cleared in K032898 (T2 Recon Nail System) as well as existing instruments previously cleared in K123401 (Gamma 3 and T2 Recon Targeting Devices), K131365 (T2 Tibial Nailing 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.

IMN Screws System

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

IMN Instruments System

The IMN Instruments System includes instruments that support the implantation and extraction of intramedullary nails and screws. The IMN Instruments System is intended for use with T2 Alpha Femur Antegrade GT/PF Nailing System and IMN Screws System.

V. INTENDED USE

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.

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.

VI. INDICATION FOR USE

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

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.

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

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 Recon Nail System (K102992), T2 GTN System (K101438) and Zimmer Natural Nail System (K083497) 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 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.

The following technological differences exist between the subject and predicate devices:

- Hole configurations in proximal and distal part of nail
- Locking configurations.

The differences have 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 locking screws previously cleared in Titan Tibial Nail System (K003018) 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:

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

IMN Instruments System

Device comparison demonstrated that the IMN Instruments System is substantially equivalent to the previously cleared Gamma3 and T2 Recon Target Devices (K123401) 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:

- Used for guided distal locking of nails
- Design consisting of distal targeting arm and adjusting device
- Manufactured from Stainless Steel, PEEK unreinforced as well as PEEK with carbon fibers.

The following technological differences exist between the subject and predicate devices:

- A single adjusting device to cover all potential locking options.

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

VIII. PERFORMANCE DATA

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

T2 Alpha Femur Antegrade GT/PF Nailing System

Non-clinical testing was performed for the T2 Alpha Femur Antegrade GT/PF Nailing System under worst case scenario to determine substantial equivalence.

The following bench testing was conducted:

- Fatigue strength testing
- Testing of mechanical properties as per ASTM F1264
- Cut-out testing

Testing demonstrated that the T2 Alpha Femur Antegrade GT/PF Nailing System is equivalent in mechanical performance to the predicate devices (K102992, K101438, and K083497).

Non-clinical testing has demonstrated that the T2 Alpha Femur Antegrade GT/PF Nailing System is MR Conditional.

Biocompatibility testing was performed to evaluate the biological safety of the T2 Alpha Femur Antegrade GT/PF 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 the T2 Alpha Femur Antegrade GT/PF Nailing System is biocompatible.

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

<u>IMN Screws System</u>

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

- Testing of mechanical properties as per ASTM F543

Testing demonstrated that the IMN Screws System is equivalent in mechanical performance to the predicate device (K003018).

Non-clinical testing has demonstrated that the IMN Screws System is MR Conditional.

Biocompatibility assessment 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 IMN Screws System is biocompatible.

The Bacterial Endotoxin Testing demonstrated that the IMN Screws System meets the specified endotoxin limit.

IMN Instruments System

Biocompatibility testing was performed to evaluate the biological safety of the IMN Instruments 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 the IMN Instruments System is biocompatible.

IX. CLINICAL TESTING

T2 Alpha Femur Antegrade GT/PF Nailing System

No clinical testing of the T2 Alpha Femur Antegrade GT/PF 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.

X. CONCLUSION

T2 Alpha Femur Antegrade GT/PF Nailing System

The T2 Alpha Femur Antegrade GT/PF Nailing System is substantially equivalent to the predicate devices (K102992, K101438, and K083497) identified in this premarket notification.

IMN Screws System

The IMN Screws System is substantially equivalent to the predicate device (K003018) identified in this premarket notification.

IMN Instruments System

The IMN Instruments System is substantially equivalent to the predicate device (K123401) identified in this premarket notification.