June 11, 2019

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

Re: K191271
Trade/Device Name: T2 Alpha Femur Antegrade GT/PF Nailing System, T2 Alpha Tibia 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: May 9, 2019
Received: May 13, 2019

Dear Dr. 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. 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 CAPT Raquel Peat, PhD, MPH, USPHS
Director
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)*
K191271

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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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)*

K191271

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.

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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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)*

K191271

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.

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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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)*

K191271

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.

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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Section 9: 510(k) Summary

I. SUBMITTER

Sponsor:	Stryker Trauma GmbH Prof.-Kuentscher-Str. 1-5 24232 Schoenkirchen / Germany
Contact Person:	Dr. Heike Gustke Staff Regulatory Affairs Specialist Prof.-Kuentscher-Str. 1-5 24232 Schoenkirchen / Germany heike.gustke@stryker.com Phone: +49 4348 702 637 Fax: +49 4348 702 8637

Date Prepared:	April 15, 2019

II. DEVICE

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

	T2 Alpha Tibia 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)
	T2 Alpha Tibia 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, T2 Alpha Tibia Nailing System, IMN Screws System, IMN Instruments System (K180436)

IV. DEVICE DESCRIPTION

A Special 510(k) submission is being supplied to the U.S. FDA to gain clearance for modifications to the existing T2 Alpha Femur Antegrade GT/PF Nailing System, T2 Alpha Tibia Nailing System, IMN Screws System and IMN Instruments System previously cleared in K180436. Modifications include an increase of shelf-life from 5 years to 10 years for the sterile implants and a change of dimensional specifications for the Advanced Locking Screw, Targeting Arm Femur GT and Targeting Arm Femur PF.

The intended use and indications for use of existing T2 Alpha Femur Antegrade GT/PF Nailing System, T2 Alpha Tibia Nailing System, IMN Screws System and IMN Instruments System previously cleared in K180436 remain unchanged.

This submission encompasses multiple systems (T2 Alpha Femur Antegrade GT/PF Nailing System, T2 Alpha Tibia 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 Femur Antegrade GT/PF Nailing System

The T2 Alpha Femur Antegrade GT/PF Nailing System previously cleared in K180436 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) 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 originally cleared in K003018 (Titan Tibial Nail) that have subsequently also received clearance for use in locking femoral nailing systems (K010801), the Lag Screw Recon of T2 Recon System (K032898), the End Cap Lower Extremity and the Nail Holding Screw Tibia / Femur PF of T2 Alpha Tibia Nailing System (K180436), the locking screws and advanced locking screws of IMN Screws System (K180436), the distal targeting device femur antegrade of IMN Instruments System (K180436) as well as the surgical instruments of IMN Instruments System and T2 Instruments System (510(k) exempt devices).

T2 Alpha Tibia Nailing System

The T2 Alpha Tibia Nailing System previously cleared in K180436 is a fracture fixation system and includes sterile implants (tibial nails in various diameter, compression screw tibia and end caps) as well as non-sterile instruments (targeting devices).

The sterile implants (Tibial Nail, Compression Screw Tibia, End Cap Tibia, and End Cap Lower Extremity) are made of titanium alloy (Ti6Al4V ELI) per ASTM F136. The adapters and nail holding screws will be manufactured from stainless steel. The Targeting Arm Tibia and Adjusting Device Tibia are made of stainless steel, PEEK unreinforced as well as PEEK with 30% and 50% carbon fibers. The Distal Targeting Arm Tibia is made of PEEK with 30% and 50% carbon fibers.

The T2 Alpha Tibia Nailing System will be used with the locking screws (K003018, Titan Tibial Nail), the locking screws and advanced locking screws of IMN Screws System (K180436), the surgical instruments of T2 Tibial Nailing System (K131365) as well as the surgical instruments of IMN Instruments System and T2 Instruments System (510(k) exempt devices). Further, the End Cap Lower Extremity and the Nail Holding Screw Tibia / Femur PF of T2 Alpha Tibia Nailing System can be used with the T2 Alpha Femur Antegrade GT/PF Nailing System (K180436).

IMN Screws System

The IMN Screws System previously cleared in K180436 includes bone screws (locking screws 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) per ASTM F136. The IMN Screws System is intended for use with T2 Alpha Femur Antegrade GT/PF Nailing System, T2 Alpha Tibia Nailing System and IMN Instruments System.

IMN Instruments System

The IMN Instruments System includes the distal targeting device femur antegrade previously cleared in K180436. There are also associated surgical instruments (class I devices) 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, T2 Alpha Tibia 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.

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.

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

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.

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 Alpha Femur Antegrade GT/PF Nailing System (K180436) regarding 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) per ASTM F136,
- Set screws are manufactured from titanium alloy (Ti6Al4V ELI) per ASTM F136 and PEEK,

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

T2 Alpha Tibia Nailing System

Device comparison demonstrated that the T2 Alpha Tibia Nailing System is substantially equivalent to the previously cleared T2 Alpha Tibia Nailing System (K180436) regarding 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) per ASTM F136.
- Hole configurations in proximal and distal part of nail, and
- Locking configurations.

IMN Screws System

Device comparison demonstrated that the IMN Screws System is substantially equivalent to the previously cleared IMN Screws System (K180436) regarding 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:

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

IMN Instruments System

Device comparison demonstrated that the IMN Instruments System is substantially equivalent to the previously cleared IMN Instruments System (K180436) regarding 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.

VIII. PERFORMANCE DATA

The submitter of this Special 510(k) is the manufacturer of the predicate device.

Increase of shelf-life from 5 years to 10 years for the sterile implants

The packaging testing was performed using methods consistent with the predicate device to ensure the packaging integrity and to support that the packaging preserves the functionality and safety of the device throughout its declared shelf-life.

A risk analysis was performed as per DIN EN ISO 14971 to assess the impact of the modification on the devices. The records of risk analysis process are retained in design history file. The evaluation demonstrated that the subject device did not present a new worst case and that the same verification and validation methods were applied to the subject device in comparison to the previously cleared predicate device (K180436). The risk analysis demonstrated that the subject device is as safe and effective as the predicate device.

Change of dimensional specifications of the Advanced Locking Screw, Targeting Arm Femur GT and Targeting Arm Femur PF

The specification review and dimensional analysis were performed using the same protocol as the original submission for collecting and assessing the data. The acceptance criteria were not altered from those used for the original device. No additional types of evaluation are needed.

A risk analysis was performed as per DIN EN ISO 14971 to assess the impact of the modification on the devices. The records of risk analysis process are retained in design history file. The evaluation demonstrated that the subject device did not present a new worst case and that the same verification and validation methods were applied to the subject device in comparison to the previously cleared predicate device (K180436). The risk analysis demonstrated that the subject device is as safe and effective as the predicate device.

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.

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.

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 device (T2 Alpha Femur Antegrade GT/PF Nailing System (K180436)) identified in this premarket notification.

T2 Alpha Tibia Nailing System

The T2 Alpha Tibia Nailing System is substantially equivalent to the predicate device (T2 Alpha Tibia Nailing System (K180436)) identified in this premarket notification.

IMN Screws System

The IMN Screws System is substantially equivalent to the predicate device (IMN Screws System (K180436) identified in this premarket notification.

IMN Instruments System

The IMN Instruments System is substantially equivalent to the predicate device (IMN Instruments System (K180436)) identified in this premarket notification.