March 20, 2020

Stryker GmbH
Cindy Leon
Staff Specialist, Regulatory Affairs
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K193366
Trade/Device Name: T2 ICF
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: February 19, 2020
Received: February 20, 2020

Dear Cindy Leon:

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,

Shumaya Ali, M.P.H.
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma 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)* K193366

Device Name
T2 ICF System

Indications for Use *(Describe)*
The T2 ICF System is indicated for internal bone fixation of the foot for the following conditions and procedures:

- Neuropathic osteoarthropathy (Charcot)
- Fracture fixation
- Osteotomies
- Non-unions
- Mal-unions
- Fusions

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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510(k) Summary

Proprietary Name:	T2 ICF System
Common Name:	Smooth or Threaded Metallic Bone Fixation Fastener (21 CFR 888.3040)
Regulation Description:	Smooth or Threaded Metallic Bone Fixation Fastener (21 CFR 888.3040)
Regulation Number:	21 CFR 888.3040
Product Code:	HWC
Device Class:	Class II
Sponsor:	Stryker GMBH Bohnackerweg 1 2545 Selzach / Switzerland
Contact Person:	Cindy Leon Staff Specialist, Regulatory Affairs 325 Corporate Drive Mahwah, NJ 07430 Phone: 201-831-5374 Fax: 201-831-6500
Date Prepared:	December 03, 2019
Primary Predicate:	Synthes (USA) 6.5mm Midfoot Fusion Bolt: **K081071**
Additional Predicate:	Wright Medical Technology, Inc. SALVATION Midfoot Nail: **K180024**

Description

This Traditional 510(k) premarket notification is being supplied to the U.S. FDA to gain clearance to market the T2 ICF System. The T2 ICF System is a cannulated intramedullary nail system intended for internal fixation and stabilization of various foot instabilities and reconstructions. The T2 ICF system includes sterile packed implants (intramedullary nails and endcaps) available in various diameters and lengths to better accommodate patient anatomy as well as non-sterile instrumentation (targeting devices). The intramedullary nails are assembled with a pre-loaded compression screw, which allows for the nail to compress the bony fragments. The sterile packed intramedullary nails (including the preloaded compression screw) and endcaps are made of titanium alloy (Ti6Al4V ELI) as per ASTM F136.

Additionally, the T2 ICF System will be used with an existing subset of VariAx 2 bone screws (previously cleared under K191412) to achieve fixation of the nail. The use of this subset of the

VariAx 2 bone screws with the T2 ICF System does not alter the intended use, indications for use, or overall function of the VariAx 2 bone screws.
Lastly, the T2 ICF System will be used with several existing Class I 510(k) exempt devices for various orthopedic purposes.

Intended Use

The T2 ICF System is intended for internal bone fixation.

Indications for Use

The T2 ICF System is indicated for internal bone fixation of the foot for the following conditions and procedures:

- Neuropathic osteoarthropathy (Charcot)
- Fracture fixation
- Osteotomies
- Non-unions
- Mal-unions
- Fusions

Summary of Technologies

A comparison of the systems demonstrated that the subject T2 ICF System is substantially equivalent to the previously cleared predicate Synthes (USA) 6.5mm Midfoot Fusion Bolt (K081071) and the Wright Medical Technology, Inc. SALVATION Midfoot Nail (K180024) regarding their intended use, indications for use, technological characteristics (design features, material and performance), as well as underlying operational principles.

Overall, the subject device and the predicate devices share many of the same technological characteristics including:

- Intramedullary nailing system intended to provide fracture fixation and alignment of the foot
- Nail design (available in various size configurations) and material* (titanium alloy – Ti6Al4V ELI per ASTM F136)

*- Synthes (USA) 6.5mm Midfoot Fusion Bolt offered in both titanium alloy and stainless steel variants

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

- Fixation technology
- Nail diameter size offerings

These differences have been addressed through performance testing, which demonstrates that the subject device is as safe and effective as the predicate devices.

Non-Clinical Testing

The following bench testing was conducted to determine substantial equivalence between the subject device and the primary predicate Synthes (USA) 6.5mm Midfoot device:

1. Biocompatibility evaluation per ISO 10993-1 and FDA Guidance, "Use of International Standard ISO 10993-1, "Biological evaluation of medical device – Part 1: Evaluation and testing within a risk management process". Biocompatibility testing per ISO 10993-5, ISO 10993-12, ISO 10993-18.
2. Bacterial endotoxin testing (BET) as specified in ANSI/AAMI ST72 was used for pyrogenicity testing to achieve an Endotoxin limit of <20 EU/Device.
3. MR Compatibility:
    a. Radio frequency (RF)-Induced heating per ASTM F2182
    b. Magnetically Induced Displacement Force per ASTM F2052
    c. Magnetically Induced Torque per ASTM F2213
    d. MR Image Artifacts per ASTM F2119
4. Dynamic Cantilever Bending Test
5. Static Axial Load to Failure Test
6. Targeting Device Accuracy Testing

The results of the testing demonstrated that the subject device is substantially equivalent to the marketed predicate device.

Clinical Testing

No clinical testing of the T2 ICF System has been conducted.

Conclusion

The subject T2 ICF System is substantially equivalent to the primary predicate Synthes (USA) 6.5mm Midfoot Fusion Bolt (K081071) and the additional predicate Wright Medical Technology, Inc. SALVATION Midfoot Nail (K180024) identified as part of this premarket notification.