June 10, 2022

Stryker GmbH
Danielle Madureira, PhD
Associate Manager Regulatory Affairs
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K220319
Trade/Device Name: Asnis® III Cannulated Screw System, Asnis® PRO Cannulated Screw System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC, HTN, OUR
Dated: May 6, 2022
Received: May 9, 2022

Dear Dr. Madureira:

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)*

K220319

Device Name
Asnis® III Cannulated Screw System

Indications for Use *(Describe)*

The Asnis III 4.0 and 5.0 mm Cannulated Screws are intended for fixation of fractures, fusions, osteotomies, non-unions, and malunions of fragments of small and long bones, the pelvis and bones of the foot.

The Asnis III 6.5 and 8.0 mm Cannulated Screws are intended for:

- fracture fixation, fusions, osteotomies, nonunions, and malunions of fragments of small and long bones, the pelvis, sacrum, and bones of the foot
- sacroiliac joint fusion for conditions including sacroiliac joint disruptions

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K220319

Device Name

Asnis® PRO Cannulated Screw System

Indications for Use *(Describe)*

The Asnis PRO 6.5 and 8.0 mm Cannulated Screws are intended for:

• fracture fixation, fusions, osteotomies, nonunions, and malunions of fragments of small and long bones, the pelvis, sacrum, and bones of the foot

• sacroiliac joint fusion for conditions including sacroiliac joint disruptions

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

Proprietary Name:	Asnis® III Cannulated Screw System and Asnis® PRO Cannulated Screw System
Common Name:	Bone Screw (primary) Washer, Bolt Nut Sacroiliac Joint Fixation
Regulation Description:	Smooth or threaded metallic bone fixation fastener (primary) Single/multiple component metallic bone fixation appliances and accessories
Regulation Number:	21 CFR 888.3040 (primary), 21 CFR 888.3030
Classification Product Code:	HWC (primary), HTN, OUR
Device Class:	II
Sponsor:	Stryker GMBH Bohnackerweg 1 2545 Selzach, Switzerland
Contact Person:	Danielle Jannuzzi Madureira, PhD Associate Manager Regulatory Affairs Dr. Homer Stryker Strasse, 1 CH-2545 Selzach, Switzerland Phone: +41 79 890 02 89 Fax: +41 32 641 66 60
Date:	June 02, 2022
Primary Predicate Device:	Asnis® III Cannulated Screw System and Asnis® PRO Cannulated Screw System (K213199)
Additional Predicate Device	DePuy Synthes Trauma Screws (K192745)
Device Description:	The Asnis® III Cannulated Screw System, previously cleared in K213199, consists of self-tapping cannulated screws and the corresponding washers. All devices in the system are provided sterile and non-sterile. The thread diameters are 4.0, 5.0. 6.5, and 8.0 mm. They are either fully or partially threaded. All screws are self-drilling and self-tapping. There are corresponding washers to the 4.0 and 5.0 mm screws respectively and one washer fitting for both diameters, 6.5 and 8.0 mm. Screws and washers are made of stainless steel and titanium alloy. The Asnis® PRO Cannulated Screw System consists of self-tapping cannulated screws. All devices in the system are provided sterile and non-sterile. The thread diameters are 6.5, and 8.0 mm. They are either fully or partially threaded. All screws are self-drilling and self-tapping. There are corresponding washers to the 4.0 and 5.0 mm screws respectively and one washer fitting for both diameters, 6.5 and 8.0 mm. Screws and washers are made of stainless steel and titanium alloy. The subject of this bundled traditional submission is to clarify the indications to the Asnis® III Cannulated Screw System and Asnis® PRO Cannulated

	Screw System, cleared in K213199 and to introduce a new washer to the Asnis® PRO Cannulated Screw System cleared in K213199.
Indications for Use:	The Asnis III 4.0 and 5.0 mm Cannulated Screws are intended for fixation of fractures, fusions, osteotomies, non-unions, and malunions of fragments of small and long bones, the pelvis and bones of the foot. The Asnis III 6.5 and 8.0 mm Cannulated Screws are intended for: • fracture fixation, fusions, osteotomies, nonunions, and malunions of fragments of small and long bones, the pelvis, sacrum, and bones of the foot • sacroiliac joint fusion for conditions including sacroiliac joint disruptions The Asnis PRO 6.5 and 8.0 mm Cannulated Screws are intended for: • fracture fixation, fusions, osteotomies, nonunions, and malunions of fragments of small and long bones, the pelvis, sacrum, and bones of the foot • sacroiliac joint fusion for conditions including sacroiliac joint disruptions
Comparison to Predicate Device:	The intended use of the modified devices, as described in its labeling, has not changed because of the modifications proposed in the present submission. The clarification of the indication for use and the introduction of new washers does not alter the fundamental scientific technology shared by both the subject devices, Asnis® III Cannulated Screw System and Asnis® PRO Cannulated Screw System, and predicate device, Asnis® III Cannulated Screw System and Asnis® PRO Cannulated Screw System.
Performance Data (Nonclinical):	*Non-Clinical Performance and Conclusions:* No mechanical testing was deemed necessary as the new washers does not create a new worst case. All bench tests performed in accordance with ASTM F543 and previously presented in Asnis® III Cannulated Screw System and Asnis® PRO Cannulated Screw System (K213199), remain true and accurate. Static Cantilever Bending Test was performed according to ASTM F2193. Tests performed to establish compatibility with a magnetic resonance environment: • Magnetically Induced Displacement per ASTM F2052 • Magnetically Induced Torque per ASTM F2213 • RF Heating per ASTM F2182 • Image Artifacts per ASTM F 2119 *Clinical Performance and Conclusions:* Clinical data and conclusions were not needed for this device.
Conclusion:	The subject devices have the same intended use and indications for use as the predicate device. The subject devices use the same operating principle, incorporate the same basic design and labeling and are manufactured and sterilized using the same materials and processes as the predicate device. Except for the modifications described in this submission the subject devices are identical to the predicate device, and the performance data and analyses demonstrate that: • any differences do not raise new questions of safety and effectiveness as established with performance testing; and • the subject devices are at least as safe and effective as the legally marketed predicate devices