June 10, 2019

Stryker GmbH
Sanja Jahr
Senior Regulatory Affairs Specialist
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K183104
Trade/Device Name: Mini Cannulated Headed and Headless Screw Set
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastner
Regulatory Class: Class II
Product Code: HWC
Dated: November 7, 2018
Received: November 8, 2018

Dear Sanja Jahr:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 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,

for Shumaya Ali, MPH
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)*
K183104

Device Name
Mini Cannulated Titanium Headed and Headless Screw Set

Indications for Use *(Describe)*
The Stryker Cannulated Titanium (Ti6AL4V) Headed & Headless Mini 2.5 mm, 3.0 mm, and 4.0 mm bone screws are indicated for use in the treatment of bone fractures, osteotomies, arthrodesis, osteochondritis, and tendon reattachment in small bones and interfragmentary indications including specific long bone indications. The device is intended for, but not limited to, hand surgery, orthopedic surgery, plastic surgery, and podiatric surgery. These devices are not intended for use in the spine.
The Stryker Cannulated Titanium Headed & Headless Mini Screw Set is intended for the following surgical indications:

- Scaphoid fractures
- Lunate fractures
- Capitate fractures
- Trapezial fractures
- Metacarpal fractures
- Metatarsal fractures
- Phalangeal fractures
- Radial head fractures
- Ulnar styloid fractures
- Small joint fusion
- Osteochondral fractures
- Humeral head fractures
- Glenoid fractures
- Carpometacarpal joint fractures
- Interphalangeal joint fractures
- Tarsal fusions
- Malleolar fractures
- Patellar fractures
- Metaphyseal fractures
- Interfragmentary radius fractures
- Interfragmentary ulnar fractures
- Small hand and wrist bone fractures
- Distal metatarsal osteotomies
- Forefoot interfragmentary fractures
- Midfoot interfragmentary fractures

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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510(k) Summary

Proprietary Name:	Mini Cannulated Titanium Headed and Headless Screw Set
Common Name:	Bone Screw
Regulation Description:	Smooth or threaded metallic bone fixation fastener
Regulation Number:	21 CFR 888.3040
Product Code:	HWC
Device Class:	Class II
Sponsor:	Stryker GMBH Bohnackerweg 1 2545 Selzach / Switzerland
Contact Person:	Sanja Jahr Senior Regulatory Affairs Specialist 325 Corporate Drive Mahwah, NJ 07430 Phone: 201-831-6797 Fax: 201-831-6020
Date Prepared:	November 7, 2018
Primary Predicate:	Mini Cannulated Titanium Headed and Headless Screw Set (K120493)

Description

The Mini Cannulated Titanium Headed and Headless Screw Set consists of cannulated screws with diameters ranging from 2.5 mm to 4.0 mm. The cannulated screws have a torx head design and are made from anodized titanium alloy. This submission seeks to update labeling.

Indications for Use

The Stryker Cannulated Titanium (Ti6AL4V) Headed & Headless Mini 2.5 mm, 3.0 mm, and 4.0 mm bone screws are indicated for use in the treatment of bone fractures, osteotomies, arthrodesis, osteochondritis, and tendon reattachment in small bones and interfragmentary indications including specific long bone indications. The device is intended for, but not limited to, hand surgery, orthopedic surgery, plastic surgery, and podiatric surgery. These devices are not intended for use in the spine. The Stryker Cannulated Titanium Headed & Headless Mini Screw Set is intended for the following surgical indications:

- Scaphoid fractures

- Lunate fractures
- Capitate fractures
- Trapezial fractures
- Metacarpal fractures
- Metatarsal fractures
- Phalangeal fractures
- Radial head fractures
- Ulnar styloid fractures
- Small joint fusion
- Osteochondral fractures
- Humeral head fractures
- Glenoid fractures
- Carpometacarpal joint fractures
- Interphalangeal joint fractures
- Tarsal fusions
- Malleolar fractures
- Patellar fractures
- Metaphyseal fractures
- Interfragmentary radius fractures
- Interfragmentary ulnar fractures
- Small hand and wrist bone fractures
- Distal metatarsal osteotomies
- Forefoot interfragmentary fractures
- Midfoot interfragmentary fractures

Summary of Technologies

A comparison of the systems demonstrated that the subject Mini Cannulated Titanium Headed and Headless Bone Screw Set is substantially equivalent to the previously cleared Mini Cannulated Titanium Headed and Headless Bone Screw Set (K120493) in regard to intended use, material, design, and operational principles.

Non-Clinical Testing

This submission does not require non-clinical testing.

Clinical Testing

This submission does not require clinical testing.

Conclusion

The subject Mini Cannulated Titanium Headed and Headless Bone Screw Set is substantially equivalent to the predicate Mini Cannulated Titanium Headed and Headless Bone Screw Set (K120493).