Stryker GmbH
Jemin Dedania
Associate Manager Regulatory Affairs
325 Corporate Drive
Mahwah, New Jersey 07430

August 5, 2020

Re: K201715
Trade/Device Name: Smart Toe II, X Fuse
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HTY
Dated: June 22, 2020
Received: June 23, 2020

Dear Mr. Dedania:

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

Colin O'Neill, M.B.E.
Acting Assistant Director
DHT6B: Division of Spinal 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)*
K201715

Device Name
Smart Toe II

Indications for Use *(Describe)*
The Smart Toe II is indicated for interphalangeal fusion of the toes.

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
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Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
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"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)*

K201715

Device Name
X Fuse

Indications for Use *(Describe)*
The X Fuse is indicated for interphalangeal fusion of fingers and toes.

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:	Smart Toe II & X Fuse
Common Name:	Intramedullary Bone Fastener
Regulation Description:	Smooth or threaded metallic bone fixation fastener
Regulation Number:	21 CFR 888.3040
Product Code:	HTY
Device Class:	Class II
Sponsor:	Stryker GMBH Bohnackerweg 1 2545 Selzach / Switzerland
Contact Person:	Jemin Dedania Associate Manager Regulatory Affairs 325 Corporate Dr Mahwah, NJ 07430 Phone: (201) 831-6461 Fax: (201) 831-3803
Date Prepared:	June 22, 2020
Primary Predicate:	Memometal Intramedullary Bone Fastener (Smart Toe/X Fuse) (K112197)
Reference Devices:	Memory Metal Staples, Easyclip (K122113)

Description

The Smart Toe II & X Fuse, previously cleared in K112179, are threaded metallic bone fixation fasteners and include superelastic and body temperature activated shape memory Nitinol per ASTM F2063-18. The subject of the bundled submission introduces a new passivation step and packaging change.

Indications for Use

The Smart Toe II is indicated for interphalangeal fusion of the toes.

The X Fuse is indicated for interphalangeal fusion of fingers and toes.

Summary of Technologies

A comparison of the systems demonstrated that the subject Smart Toe II & X Fuse are substantially equivalent to the Memometal Intramedullary Bone Fastener (Smart Toe/X Fuse) [K112197], in regards to intended use, material, design, and operational principles.

Non-Clinical Testing

Non-clinical laboratory testing was performed on the worst-case subject staples to determine substantial equivalence. Testing demonstrated that the Intramedullary Bone Fastener (Smart Toe II/X Fuse) system is equivalent in mechanical performance to the predicate device, the Memometal Intramedullary Bone Fastener (Smart Toe/X Fuse) [K112197] and reference device, the Memory Metal Staples, Easyclip (K122113).

The following testing was performed:

- Four-Point Bending Testing per ASTM F564
- Cyclic Potentiodynamic Polarization (Corrosion) Test per ASTM F2129

Clinical Testing

Clinical testing was not required for this submission.

Conclusion

The subject Smart Toe II & X Fuse are substantially equivalent to the predicate Memometal Intramedullary Bone Fastener (Smart Toe/X Fuse).