DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 27, 2015

Stryker Trauma GmbH
Ms. Estela Celi
Senior Regulatory Affairs Specialist
325 Corporate
Mahwah, New Jersey 07430

Re: K143063
Trade/Device Name: Stryker SonicPin System
SonicAnchor System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HTY, MAI, GAT
Dated: October 22, 2014
Received: October 29, 2014

Dear Ms. Celi:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143063

Device Name
Stryker SonicPin System

Indications for Use *(Describe)*
The Stryker SonicPin System is intended to maintain alignment and fixation of bone fractures, osteotomies or bone grafts in hallux valgus applications in the presence of appropriate immobilization (e.g. rigid fixation implants, cast and brace). The Stryker SonicPin is designed only to be inserted with the SonicFusion equipment.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K143063

Device Name
Stryker SonicAnchor System

Indications for Use *(Describe)*

The Stryker SonicAnchor System is intended to be used for suture or tissue fixation in open procedures in the foot, ankle, knee, hand, wrist, elbow and shoulder. The Stryker SonicAnchor is designed only to be inserted with the SonicFusion equipment.
Indications Include:

Foot/Ankle
- Achilles Tendon Repair
- Lateral Stabilization
- Medial Stabilization
- Hallux Valgus Reconstruction
- Midfoot Reconstruction
- Metatarsal Ligament Repair
- Digital Tendon Transfer

Shoulder
- Acromio-Clavicular Separation Repair
- Proximal Deltoid Repair

Elbow
- Ulnar or Radial Collateral Ligament Reconstruction

Knee
- Patellar Tendon Repair

Hand/Wrist
- Scapholunate Ligament Reconstruction
- Carpal Ligament Reconstruction
- Repair/Reconstruction of Collateral Ligaments

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

Submitter:	Stryker Trauma GmbH Prof. Kuetscher Str. 1-5 24232 Schönkirchen Germany Phone: (201) 831-6461 Fax: (201) 831-3461
Contact Person:	Estela Celi Senior Regulatory Affairs Specialist
Device Name of Device:	Stryker SonicPin System/SonicAnchor System
Common Name:	Stryker SonicPin System- Smooth Fixation Pin Stryker SonicAnchor System-Smooth Fixation Pin/Fastener & Suture
Classification Name:	Stryker SonicPin System Smooth or threaded metallic bone fixation fastener 21 CFR §888.3040 Stryker SonicAnchor System Single/multiple component metallic bone fixation appliances and accessories. 21 CFR §888.3030 Nonabsorbable poly(ethylene terephthalate) surgical suture 21 CFR §878.5000
Regulatory Class:	II
Product Code:	Stryker SonicPin System: HTY Stryker SonicAnchor System: MAI, GAT
Predicate Devices:	Stryker SonicPin System Primary Predicate: Stryker SonicPin System-K091955 Stryker SonicAnchor System Primary Predicate-Arthrex 2.5 mm PushLock -K063479 Reference Device- Stryker SonicPin System-K091955
Date Prepared:	October 22, 2014

Description:

Stryker SonicPin System
This Traditional 510(k) submission is being supplied to the U.S. FDA to seek clearance for modifications made to the Stryker SonicPin System, with regard to the SonicFusion equipment and included in the previously cleared Stryker SonicPin System under K091995 and the addition of accessories. The Stryker SonicPin System consists of a sterile bioresorbable pin implant, the SonicFusion equipment and associated accessories intended for the internal fixation of bone fractures and fragments. The pin is made of PLDLLA (Poly(L-lactide-co-D,L-lactide) which has been evaluated for magnetic resonance safety and is implanted using SonicFusion technology which is a process that employs ultrasonic energy to liquefy a polymer and facilitate a fixed interface between the implant and host bone.

The associated accessories include:
- SonicFusion equipment
- Drill
- Handpiece Tip
- TipTool
- Direct Depth Gauge

Stryker SonicAnchor System
This Traditional 510(k) submission is being supplied to the U.S. FDA to provide authorization to market the new Stryker SonicAnchor System. The Stryker SonicAnchor System consists of a bioresorbable anchor with suture implant, the SonicFusion equipment and associated accessories intended for the fixation of suture or soft tissue to cancellous bone. The implant is comprised of the anchor, made of PLDLLA (Poly(L-lactide-co-D,L-lactide) which has been evaluated for magnetic resonance safety and a Teleflex Force Fiber suture, made of braided ultrahigh molecular weight polyethylene (UHMWPE) and polypropylene (PP) strands.
The associated accessories include:
- SonicFusion equipment
- Drill
- Handpiece Tip
- TipTool

Intended Use:

Stryker SonicPin System
The Stryker SonicPin System is intended to maintain alignment and fixation of bone fractures, osteotomies or bone grafts in hallux valgus applications in the presence of appropriate immobilization (e.g. rigid fixation implants, cast and brace). The Stryker SonicPin is designed only to be inserted with the SonicFusion equipment.

Both the subject and predicate have the same intended use for the internal fixation of bone fractures and fragments.

Stryker SonicAnchor System
The Stryker SonicAnchor System is intended to be used for suture or tissue fixation in open procedures in the foot, ankle, knee, hand, wrist, elbow and shoulder. The Stryker SonicAnchor is designed only to be inserted with the SonicFusion equipment.

Both the subject and predicate have the same intended use for the fixation of suture or soft tissue to cancellous bone.

Indications for Use:

Stryker SonicPin System
The Stryker SonicPin System is intended to maintain alignment and fixation of bone fractures, osteotomies or bone grafts in hallux valgus applications in the presence of appropriate immobilization (e.g. rigid fixation implants, cast and brace). The Stryker SonicPin is designed only to be inserted with the SonicFusion equipment.

Stryker SonicAnchor System
The Stryker SonicAnchor System is intended to be used for suture or tissue fixation in open procedures in the foot, ankle, knee, hand, wrist, elbow and shoulder. The Stryker SonicAnchor is designed only to be inserted with the SonicFusion equipment.
Indications Include:

Foot/Ankle
- Achilles Tendon Repair
- Lateral Stabilization
- Medial Stabilization
- Hallux Valgus Reconstruction
- Midfoot Reconstruction
- Metatarsal Ligament Repair
- Digital Tendon Transfer

Shoulder
- Acromio-Clavicular Separation Repair
- Proximal Deltoid Repair

Elbow
- Ulnar or Radial Collateral Ligament Reconstruction

Knee
- Patellar Tendon Repair

Hand/Wrist
- Scapholunate Ligament Reconstruction
- Carpal Ligament Reconstruction
- Repair/Reconstruction of Collateral Ligaments

Comparison of Technological Characteristics with the Predicate Device:

Stryker SonicPin System
SonicFusion is the technological principle for both the subject Stryker SonicPin System and the predicate Stryker SonicPin System. SonicFusion technology is based on the application of controlled ultrasonic energy which liquefies the polymer implant as it is placed in the bone.
At a high level, the subject and predicate devices are based on the following same technological elements:

- Use of a polymer pin implant
- SonicFusion technology used for implant application

The following differences exist between the subject and predicate devices:

- SonicPin implant material has been evaluated for magnetic resonance safety
- New SonicFusion ultrasonic generator, handpiece and footswitch
- Use of interchangeable tips on the SonicFusion handpiece
- Ultrasound delivered has a decreased amplitude
- Added footswitch containing power switch to SonicFusion equipment

Stryker SonicAnchor System
The Stryker SonicAnchor System and the predicate device are both intended to be used for suture or tissue fixation to bone.
At a high level, the subject and predicate devices require the following same technological elements:

- Surgical site preparation
- Use of a drill for surgical site preparation
- Use of a suture

The following differences exist between the subject and predicate devices:

- Use of different fixation methods

Performance Data:

Mechanical Testing

Stryker SonicPin System
Mechanical testing was performed to evaluate the implantation process with the modifications made to the SonicFusion equipment.

- Tensile Strength Testing

Additionally the magnetic resonance was evaluated as per FDA Guidance for Industry and FDA Staff - Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment, 2008.

Stryker SonicAnchor System
Testing was completed to evaluate mechanical performance of the subject device compared against the predicate.

- Dynamic Fatigue Strength Testing

Additionally the magnetic resonance safety and ultrasound heat safety were evaluated as per FDA Guidance for Industry and FDA Staff - Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment, 2008.

Biocompatibility Testing
The biocompatibility evaluation for the Stryker SonicPin System and Stryker SonicAnchor System was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The battery of testing included the following tests:

Stryker SonicPin System
- Rationales for Irritation and Sensitization testing
- Cytotoxicity
- Biological Compatibility Risk Assessment

Stryker SonicAnchor System
- Rationales for Irritation and Sensitization testing
- Cytotoxicity
- Genotoxicity
- Biodegradation
- Biological Compatibility Risk Assessment

Electrical safety and electromagnetic compatibility (EMC)
Electrical safety and EMC testing were conducted on the SonicFusion equipment used in both the Stryker SonicPin System and the Stryker SonicAnchor System, consisting of the ultrasonic generator, handpiece and footswitch. The SonicFusion equipment complies with the IEC 60601-1 standards for safety and the IEC 60601-1-2 Edition 3: 2007-03 standards for EMC.

Software Verification and Validation Testing
Software verification and validation testing was completed on the SonicFusion equipment, used in both the Stryker SonicPin System and the Stryker SonicAnchor System, was conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level of concern, since a failure or latent flaw in the software could directly result in serious injury or death to the patient or operator.

Clinical Testing:
Stryker SonicPin System
Clinical testing was not required to support substantial equivalence of the proposed Stryker SonicPin System to the predicate SonicPin System.

Stryker SonicAnchor System
Clinical testing was not required to support substantial equivalence of the Stryker SonicAnchor System in comparison to the predicate device.

Conclusion:
Stryker SonicPin System
Modifications made to the Stryker SonicPin System have been evaluated in comparison to the predicate device and non-clinical data have been used to support substantial equivalence. The hardware and software verification and validation for the SonicFusion equipment demonstrate that the subject Stryker SonicPin System should perform as intended in the specified use conditions.

Stryker SonicAnchor System
The non-clinical data for the Stryker SonicAnchor System including the SonicFusion equipment support the safety of the device and demonstrates that the Stryker SonicAnchor System performs comparably to the predicate device that is currently marketed for the same intended use.