April 30, 2019

Orthofix Inc.
Ms. Jacki Koch
Senior Regulatory Affairs Specialist
3451 Plano Parkway
Lewisville, Texas 75056

Re: K183342
Trade/Device Name: SambaScrew 3D SI Fusion System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: OUR
Dated: April 1, 2019
Received: April 2, 2019

Dear Ms. Koch:

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 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K183342

Device Name
SambaScrew 3D SI Fusion System

Indications for Use *(Describe)*
The SambaScrew 3D SI Fusion System is intended for fixation of sacroiliac joint disruptions, and intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.

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.

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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."

510(k) SUMMARY

SambaScrew 3D SI Fusion System

510(k) Owner Information

Name:	Orthofix Inc.
Address:	3451 Plano Parkway Lewisville, TX 75056
Telephone Number:	214.937.2100
Fax Number:	214-937-3322
Email:	jackikoch@orthofix.com
Registration Number:	2183449
Contact Person:	Jacki Koch, Senior Regulatory Affairs Specialist
Date Prepared:	April 1, 2019

Name of Device

Trade Name / Proprietary Name:	SambaScrew 3D SI Fusion System
Common Name:	Sacroiliac Joint Fixation Bone
Product Code:	OUR
Regulatory Classification:	Class II – 21 CFR § 888.3040
Review Panel:	Orthopedic Device Panel
Primary Predicate Device:	K121148 – SAMBA Screw System – Orthofix Inc.
Additional Predicate Devices:	K151818 – Simmetry Sacroiliac Joint Fusion System – Zyga Technology, Inc. K182983 – iFuse Implant System – SI-Bone, Inc.
Reference Devices:	K172437 – CONSTRUX Mini PEEK Ti Spacer System – Orthofix Inc.

Reason for 510(k) Submission:
Orthofix is submitting this **Traditional 510(k) premarket notification** for the new SambaScrew 3D SI Fusion System.

Device Description
The SambaScrew 3D SI Fusion System is a temporary, multiple component system consisting of non-sterile instruments as well as sterile, 11mm and 12mm cannulated screws of various lengths featuring multiple fenestrations along the shaft. The 11mm cannulated screw features a

tapered proximal end and dual-pitch threads while the 12mm cannulated screw features a single pitch thread on the proximal and distal ends. The SambaScrews are constructed from medical-grade titanium alloy (Ti-6Al-4V ELI). The 11mm and 12mm SambaScrews are 3D printed with a mid-shaft porous region. The porous titanium region has open macroscopic 3D pores with a microscopic roughened surface. SambaScrew allows for packing of autograft and allograft materials.

Indications for Use
The SambaScrew 3D SI Fusion System is intended for fixation of sacroiliac joint disruptions, and intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.

Summary of the Technological Characteristics of the Device Compared to the Selected Predicate Devices
The technological characteristics of the SambaScrew 3D SI Fusion System is similar to the predicate devices in terms of design, dimensions, intended use, materials, and performance characteristics. There are no significant differences between the SambaScrew 3D SI Fusion System and the predicate devices which would adversely affect the use of the product.

PERFORMANCE DATA – Summary of Non-Clinical Test Conducted for Determination of Substantial Equivalence
Mechanical testing consisting of Static and Dynamic cantilever beam Test, Static Torsion Test and Static Axial Pull-Off Test were conducted in accordance to ASTM F2193 Standard Specifications and Test Methods for Components Used in the Surgical Fixation of the Spinal Skeletal System and in accordance to ASTM F543 Standard Specification and Test Methods for Metallic Medical Bone Screws.

Table 1: Mechanical Performance Testing

Subject Device	Mechanical Testing
SambaScrew 3D SI Fusion implants	Static cantilever beam test per ASTM F2193-18a Standard Specifications and Test Methods for Components Used in the Surgical Fixation of the Spinal Skeletal System
SambaScrew 3D SI Fusion implants	Dynamic cantilever beam test per ASTM F2193-18a Standard Specifications and Test Methods for Components Used in the Surgical Fixation of the Spinal Skeletal System
SambaScrew 3D SI Fusion implants	Static torsion test per ASTM F543-17, Standard Specification and Test Methods for Metallic Medical Bone Screws
SambaScrew 3D SI Fusion implants	Static axial pull-off test per ASTM F543-17 Standard Specification and Test Methods for Metallic Medical Bone Screws

Basis of Substantial Equivalence
The new SambaScrew 3D SI Fusion System has the same intended use, the same indications for use, the same technological characteristics and design, same materials and the same principles of operation as the predicate SAMBA Screw System (K121148), the SImmentry Sacroiliac Joint Fusion System (K151818) and the iFuse Implant System (K162733).