April 2, 2020

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

Re: K200696
Trade/Device Name: FIREBIRD 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: March 16, 2020
Received: March 17, 2020

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/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,

Colin O'Neill, MBE
Assistant Director (Acting)
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K200696

Device Name
FIREBIRD SI Fusion System

Indications for Use *(Describe)*

The FIREBIRD 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.

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510(k) SUMMARY

FIREBIRD SI Fusion System
(Formally 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:	March 16, 2020

Name of Device

Trade Name / Proprietary Name:	FIREBIRD SI Fusion System
Common Name:	Sacroiliac Joint Fixation Bone Screw
Product Code:	OUR
Regulatory Classification:	Class II – 21 CFR § 888.3040
Review Panel:	Orthopedic Device Panel
Primary Predicate:	K183342 – SambaScrew 3D SI Fusion System
Reference Device:	K121148 – SAMBA Screw System

Reason for 510(k) Submission: Due to advancements in surgeon requests, Orthofix is submitting this Special 510(k) premarket notification for the addition of the following device below to the previously cleared SambaScrew 3D SI Fusion System (K183342) now branded as the FIREBIRD SI Fusion System:

- Addition of new 9mm FIREBIRD SI Screws

Device Description

The FIREBIRD SI Fusion System (formally SambaScrew 3D SI Fusion System) is a temporary multiple component system consisting of non-sterile instruments, sterile 11mm and 12mm FIREBIRD SI Screws and non-sterile 9mm FIREBIRD SI Screws. The FIREBIRD SI Screws are manufactured from medical-grade titanium alloy (Ti-6Al-4V ELI) with lengths ranging from 25mm to 70mm.

The 11mm FIREBIRD SI Screw is a cannulated screw featuring multiple fenestrations along the shaft, with a tapered proximal end and dual-pitch threads. The 12mm FIREBIRD SI Scew is a cannulated screw featuring multiple fenestrations along the shaft, with a single pitch thread on the proximal and distal ends. The 11mm and 12mm FIREBIRD SI Screws are 3D printed with a mid-shaft porous region. The porous titanium region has open macroscopic 3D pores with a microscopic roughened surface. The 9mm FIREBIRD SI Screw features multiple fenestrations along the shaft and maintains a single pitch thread along the proximal and distal ends of the screw.

The FIREBIRD SI Fusion System allows for packing of autograft and allograft materials.

Intended Use / Indications for Use
The FIREBIRD 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 FIREBIRD SI Fusion System are similar to the predicate (K183342 SambaScrew 3D SI Fusion System) in terms of intended use, indication for use and patient population. The subject 9mm FIREBIRD SI Screws are similar to the reference device (K121148 SAMBA Screw System) in terms of design and performance characteristics.

The technical characteristics of the subject device present no significant differences between the predicate and reference 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	Appendix
9mm FIREBIRD SI Screws	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	Appendix B: Static Cantilever Beam Testing 10117508AA
	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	Appendix C: Dynamic Cantilever Beam Testing 10117509AA
	Static torsion test per ASTM F543-17 Standard Specification and Test Methods for Metallic Medical Bone Screws	Appendix D: Static Torsion Testing 10117507AA

	Static axial pullout test per ASTM F543-17 Standard Specification and Test Methods for Metallic Medical Bone Screws	Appendix E: Static Axial Pullout Testing 10117506AA

Conclusions

The addition of the 9mm FIREBIRD SI Screws to the previously cleared FIREBIRD SI Fusion System (formally known as SambaScrew 3D SI Fusion System) does not change the previously cleared (K183342) indications for use, intended use, contraindications, warnings or precautions. Furthermore, the surgical approach and implantation technique remains the same as previously cleared (K183342).

The performance and technological characteristics of the subject device are similar to the reference device (K121148) in terms of design, materials and performance characteristics.

There are no significant differences between the subject device, predicate device and reference device, which would adversely affect the use of the product.