November 18, 2020

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

Re: K203138
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: October 19, 2020
Received: October 20, 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, M.B.E.
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)*

K203138

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,
- degenerative sacroiliitis,
- to augment immobilization and stabilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion and
- Acute, non-acute, and non-traumatic fractures involving the sacroiliac joint.

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

Telephone Number:	214-937-2100
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Email:	jackikoch@orthofix.com

Registration Number:	2183449
Contact Person:	Jacki Koch, Senior Regulatory Affairs Specialist
Date Prepared:	October 19, 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:	K201664 – Orthofix Inc. – FIREBIRD SI Fusion System
Reference Device:	K193524 – SI-Bone, Inc. – SI-BONE iFuse Implant System

Device Description

The FIREBIRD 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-6AI-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.

The principle of operation is based on the bone screw implants which are designed to prevent and minimize motion / micro motion of the sacroiliac (SI) joint, and thereby stabilize the joint or fracture. The mechanism of action is that the interference fit allows for fixation, stabilization and fusion.

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,
- degenerative sacroiliitis,
- to augment immobilization and stabilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion and
- Acute, non-acute, and non-traumatic fractures involving the sacroiliac joint.

Summary of Substantial Equivalence
There are no changes to the technological characteristics of the device that are the subject of this 510(k). The FIREBIRD SI Fusion System implants are technologically identical to and has the same intended use and substantially similar indications for use as the previously cleared predicate devices (K201664; as well as the reference predicate cleared in K193524). The proposed indications for use statement does not introduce any new indications, does not alter the therapeutic effect or use of the implants and does not expand use of the implants beyond uses contemplated under the cleared predicate (510(k)s. In conclusion, the FIREBIRD SI Fusion System with clarified indication for use statement is substantially equivalent to the predicate devices.

Summary of Verification and Validation Activities
There were no changes in the design, technological features, intended use or overall risks associated with the FIREBIRD SI Fusion System. Therefore, no new design verification or validation testing was required; the design verification and validation testing previously conducted and submitted in previously cleared FIREBIRD SI Fusion System 510(k)s is applicable (K201664, K200696 and K183342).

Orthofix follows established quality system and design control requirements in accordance with the Quality System Regulation (21 CFR 820) and declares conformance to design controls and risk-based assessment procedures, including Hazards Analysis and FMEA assessments.

Conclusion
The intended use and the technological characteristics are unchanged compared to the predicate device; therefore, the subject device is substantially equivalent to the predicate device.