



September 15, 2020

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

Re: K201664
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: June 18, 2020
Received: June 19, 2020

Dear Jacki 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.
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

Indications for Use

510(k) Number (if known)

K201664

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.

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510(k) SUMMARY

FIREBIRD 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: September 15, 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 Smooth or threaded metallic bone fixation fastener

Review Panel: Orthopedic Device Panel

Primary Predicate: K200696 – Orthofix Inc. – FIREBIRD SI Fusion System

Reference Predicate Device: K200052 – Orthofix Inc. – PTC Systems Product Claims

Reason for 510(k) Submission:

This 510(k) submission was submitted to add nano-scale descriptors to the labeling in accordance with the FDA Guidance Document “Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology.” Orthofix FIREBIRD SI Fusion System demonstrates the requirements for nanotechnology. The FIREBIRD SI Fusion System surface has been deliberately manipulated to produce nanoscale dimensions which exhibit specific properties.

The previously cleared indications for use, intended use, design, specifications, contraindications, warnings or precautions remain the same as previously cleared under K200696.

Furthermore, the surgical approach and implantation technique remain the same as previously cleared under K200696.

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 Screw 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 unchanged since the prior clearance K200696.

PERFORMANCE DATA – Summary of Non-Clinical Test Conducted for Determination of Substantial Equivalence

The performance data of the FIREBIRD SI Fusion System are unchanged since the prior clearance K200696. No new mechanical testing was performed for the FIREBIRD SI Fusion System as there are no design changes to the device.

Nano-surface descriptors are supported by surface characterization and in vitro cellular studies using HMSCs and normal human osteoblasts (NHOst) cells previously cleared under the predicate K200052. The in vitro study results cleared under the predicate K200052 demonstrated that the PTC modified surface experienced an increased proliferation and alkaline phosphatase activity (an early osteogenic differentiation marker) in human stem cells compared to the other surfaces.

The representative surface characterization and in vitro studies from the predicate K200052 substantiate the proposed labeling changes due to equivalent design, material and manufacturing processes.

Conclusion

The FIREBIRD SI Fusion System continues to utilize the same intended use, indications for use, the same technological characteristics and design, same materials and the same principles of operation as previously cleared under K200696.