April 11, 2022

OrthoFundamentals, LLC
Howard Schrayer
Regulatory Consultant
8 Lookout
Hilton Head Island, Massachusetts 29928

Re: K212962
Trade/Device Name: TRELLIS™ SI Joint 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 8, 2022
Received: March 9, 2022

Dear Howard Schrayer:

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

INDICATIONS FOR USE

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212962

Device Name
TRELLIS™ SI Joint Fusion System

Indications for Use *(Describe)*

The OrthoFundamentals TRELLIS™ SI Joint Fusion and Stabilization Implant 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
(PER 21 CFR 807.92)

General Company Information

Name: OrthoFundamentals, LLC
Contact: Howard Schrayer
Address: 173 Governors Avenue
Medford, MA 02155
Telephone: 609.273.7350

Date Prepared: April 11, 2022

General Device Information

Product Name: TRELLIS™ SI Joint Fusion System

Classification: Smooth Or Threaded Metallic Bone Fixation Fastener
Product code: OUR – Class II
21 CFR 888.3040

Predicate Device

Primary Predicate

OrthoFix	Firebird SI 510(k) K203138

Additional Predicates

Synthes	6.5mm Cannulated Screw 510(k) K029132
Keystone Dental	Genesis Implant System 510(k) K101545
SI Bone	iFuse Implant System 510(k) K193524
Globus	SI-LOK Sacroiliac Joint Fixation System 510(k) K183119
Zyga Technology, Inc	SImmetry Sacroiliac Joint Fusion System 510(k) K141549

Device Description

The TRELLIS™ SI Joint Fusion System is a multiple component system consisting of sterile single use accessory instruments and sterile individually packaged screws of various lengths and diameters. The screws are designed to compress and stabilize the sacroiliac joint during the fusion process. They are self-tapping and are designed with a porous mid-shaft region to allow bone to grow onto and into its surface. The cannulated screws have axial fenestrations that allow bone through growth and packing with autograft bone or allograft material. The screws are designed to promote bony fusion onto and into the implant through the macro-surface topography which is generated through EBM additive manufacturing. The fenestration geometry harvests autograft during insertion which helps create an environment for bony in-growth and on-growth.

Indications for Use

The OrthoFundamentals TRELLIS™ SI Joint Fusion System is indicated 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.

Substantial Equivalence
Bench Testing

A series of laboratory studies (bench tests) have been conducted to verify the suitability of the TRELLIS™ SI Joint Fusion System for its intended use, establish Substantial Equivalence with the predicate devices and confirm the reproducibility of packaging.

These tests include:

Test	Finding
Screw Pull-Out Force Testing	Substantially Equivalent
Insertion and Removal Torque Testing	Pass
Torsion Properties Testing	Substantially Equivalent
Static and Fatigue Bend Testing	Substantially Equivalent
Package Seal Strength Verification	Pass
Surface Characterization	Substantially Equivalent
Biocompatibility Justification	Pass
Component Testing Plan and Justification for Test Coupon Location	Pass
Porous Surface Lattice Abrasion Resistance	Pass
Porous Surface Lattice Stereological Evaluation	Pass
Porous Surface Lattice Mechanical Testing	Pass

Similarities and Differences

OrthoFundamentals **TRELLIS™ SI Joint Fusion System** **510(k) TBD**	**Synthes** **6.5mm Cannulated Screw** **510(k) K021932**	**OrthoFix** **Firebird SI** **510(k) K203138**
	Similarities	
Indicated for fixation of sacroiliac joint disruptions, and intended for sacroiliac joint fusion	Indicated for SI joint disruptions	Indicated for fixation of sacroiliac joint disruptions, and intended for sacroiliac joint fusion
Product Code: Class II 21 CFR 888.3040	Product Code: Class II 21 CFR 888.3040	Product Code: Class II 21 CFR 888.3040
Prescription use in OR setting	Prescription use in OR setting	Prescription use in OR setting
Cannulated screw-based implant for implantation over a k-wire	Cannulated screw-based implant for implantation over a k-wire	Cannulated screw-based implant for implantation over a k-wire
Implant uses threads for primary means of fixation	Implant uses threads for primary means of fixation	Implant uses threads for primary means of fixation
Implant is available in a variety of lengths and diameters	Implant is available in a variety of lengths	Implant is available in a variety of lengths and diameters
Device is fabricated from Titanium-6Aluminum-4Vanadium ELI per ASTM F3001-14	Device is fabricated from stainless steel or titanium alloy	Device is fabricated from Titanium-6Aluminum-4Vanadium ELI per ASTM F3001-14
Device is additively manufactured	Device is traditionally machined	Device is additively manufactured
Device is available in 9mm and 11mm diameters	Device is available in 6.5mm diameters	Device is available in 9mm, 11mm and 12mm diameters
Device is available in lengths 30mm to 70mm	Device is available in lengths 30mm to 200mm	Device is available in lengths 25mm to 70mm
Device is provided with single-use, sterile accessory delivery tools	Device provided with non-sterile accessories	Device provided with non-sterile accessories that may be resterilized (9mm screw is also non-sterile)

Device is provided sterile by gamma radiation and stored at room temperature for single patient use	Device is provided non-sterile	Device is provided in sterile and non-sterile configurations
Initial shelf-life of 1 year based on packaging validations	No shelf-life provided	No shelf-life provided

Performance Data

No animal or clinical testing has been conducted.

This submission supports the position that the OrthoFundamentals TRELLIS™ SI Joint Fusion System is substantially equivalent to the Primary and Additional predicates listed above. A number of other predicate devices list the same range of clinical uses. See above for specific non-clinical testing conducted to demonstrate substantial equivalence of the TRELLIS™ SI Joint Fusion System.

Conclusions

OrthoFundamentals, LLC believes that the information provided establishes that similar legally marketed devices have been used for the same clinical application as the TRELLIS™ SI Joint Fusion System. The device is substantially equivalent to the referenced predicates.