June 24, 2022

Cutting Edge Spine, LLC
Kyle Kuntz
Manager R&D
6012 Waxhaw Hwy
Mineral Springs, North Carolina 28108

Re: K214123
Trade/Device Name: T-FIX® 3DSI 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: May 18, 2022
Received: May 20, 2022

Dear Kyle Kuntz:

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,

for

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K214123

Device Name
T-FIX® 3DSI Joint Fusion System

Indications for Use *(Describe)*
The T-FIX® 3DSI Joint 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 of 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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5. 510(k) Summary

I. SUBMITTER

Date Prepared: 5-18-22

Applicant:
Cutting Edge Spine, LLC
6012 Waxhaw Hwy
Mineral Springs, NC 28108

Contact Person: Kyle Kuntz, Manager R&D
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Application Correspondents:
Contact Person: Kyle Kuntz, Manager R&D
Tel: (704) 243-0892
e-mail: k.kuntz@cuttingedgespine.com

Alternate Contact: Brad Roof, Quality Manager
Tel: (704) 243-0892
e-mail: b.roof@cuttingedgespine.com

II. DEVICE

Trade Name:	T-FIX® 3DSI Joint Fusion System
Common or Usual Name:	Sacroiliac Joint Fixation Device
Classification Name:	Per 21 CFR as follows: 888.3040: Smooth or threaded metallic bone fixation fastener
Regulatory Class:	II
Product Codes:	OUR

CUTTING EDGE SPINE

III. PREDICATE DEVICES

	510(k) Number	Device	Manufacturer
Primary Predicate	**K203138**	**FIREBIRD SI Fusion System**	**Orthofix Inc.**
Additional Predicate	**K190025**	**EVOL® SI Joint Fusion System**	**Cutting Edge Spine, LLC**
Additional Predicate	**K181881**	**Outlet Sacroiliac Joint Fusion System**	**SIJ Surgical**

IV. DEVICE DESCRIPTION

The T-FIX® 3DSI Joint Fusion System, a line extension of the EVOL® -SI Fusion System (K190025), is intended to treat dysfunctions of the sacroiliac joint. The subject T-FIX® 3DSI Joint Fusion System includes cannulated, 3D printed, titanium alloy bone screws as well as a full complement of instruments to place them in the body. The subject T-FIX® screw is headless so that it may be implanted with a zero profile. The distal portion of the screw has a single lead thread and the proximal end has a double lead thread. The subject T-FIX® is designed to cross the sacroiliac joint anchoring the sacrum to the pelvis thereby preventing motion of the sacroiliac joint. The subject T-FIX® screws are made from a titanium alloy Ti-6Al-4V Grade 23 per ASTM 3001 and offered with a HA nano surface treatment.

V. INDICATIONS FOR USE

The T-FIX® 3DSI Joint 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 of thoracolumbar fusion and
- acute, non-acute and non-traumatic fractures involving the sacroiliac joint

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICES

Documentation was submitted which demonstrated that the T-FIX® 3DSI Joint Fusion System, a line extension of the EVOL® -SI Fusion System (K190025) is substantially equivalent to the predicate devices based on a comparison of the following characteristics:

- Same FDA product codes
- Same Indications for Use
- Same Structural Support Mechanism
- Same Surgical Approach
- Anatomical Region: SI Joint
- Same Implant Materials
- Similar Product Dimensions
- Equivalent Mechancial Performance
- All Available by prescription only
- All Made for single use
- Same Sterilization
- Similar Technology

VII. NON-CLINICAL AND CLINICAL PERFORMANCE TESTING

Mechanical Testing

Testing was performed for the T-FIX® 3DSI Joint Fusion System and demonstrated substantial equivalent performance to the identified predicates. The mechanical tests were performed in accordance to these test methods:

Static cantilever bending, Axial Pullout, Torque to Failure, and Dynamic cantilever bending

- ASTM F543
- ASTM F2193

In all, the biomechanical testing results demonstrate that the T-FIX® 3DSI Joint Fusion System is substantially equivalent to the predicate device.

Non-Pyrogenicity Endotoxin Testing

The bacterial endotoxin test, also known as Limulus Amebocyte Lysate (LAL) on the worst case subject EVOL® -SI Joint Fusion System implants verify that the subject implants (line extension T-FIX® 3DSI) meet the 20 endotoxin units (EU)/device pyrogen limit specification, as outlined in ANSI/AAMI ST72, Bacterial endotoxins – Test methods, routine monitoring, and alternatives to batch testing and USP <161>, Transfusion and Infusion Assemblies and Similar Medical Devices.

VIII. CONCLUSIONS

Based upon a comparison of technological characteristics, intended use, design features, and mechanical performance, the T-FIX® 3DSI Joint Fusion System does not raise any new safety or efficacy concerns and has demonstrated substantial equivalence to the identified predicates.