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

April 5, 2023

Re: K230689
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: March 13, 2023
Received: March 13, 2023

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,

Eileen Cadel -S
Digitally signed by Eileen Cadel -S
Date: 2023.04.05 17:08:12 -04'00'

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)*

K230689

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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510(k) Summary

I. SUBMITTER

Date Prepared: 3/13/2023

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:
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Tel: (704) 243-0892
e-mail: k.kuntz@cuttingedgespine.com

Alternate Contact: Brad Roof, Director of Operations
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

III. PREDICATE DEVICE

	510(k) Number	Device	Manufacturer
Primary Predicate	**K214123**	**T-FIX™ 3DSI Joint Fusion System**	**Cutting Edge Spine**

IV. DEVICE DESCRIPTION

V. 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 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 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. T-FIX™ is designed to cross the sacroiliac joint anchoring the sacrum to the pelvis thereby preventing motion of the sacroiliac joint. The 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 when packaged sterile.

VI. INDICATIONS FOR USE

There are no differences between the subject device and the predicate with respect to indications and intended use.

Indications for both the subject device and the predicate:

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

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICES

Documentation was submitted which demonstrated that the T-FIX™ 3DSI Joint Fusion System is substantially equivalent to the predicate devices based on a comparison of the following characteristics:

- FDA product codes
- Indications for Use
- Surgical Approach
- Anatomical Region
- Implant Materials
- Product Dimensions
- Mechancial Performance
- Available by prescription only
- Made for single use
- Sterility Assurance Level (SAL)
- Technology

VIII. NON-CLINICAL AND CLINICAL PERFORMANCE TESTING

Additional testing was performed to determine that Steam as a sterilization method will not impact the safety or efficacy of this implant. A summary of the test data is included.

IX. CONCLUSIONS

Based upon a comparison of technological characteristics, intended use, design features, and mechanical performance, the addition of steam sterilization to the T-FIX™ 3DSI Joint Fusion System does not raise any new concerns of safety or efficacy. The data presented in this submission demonstrates that the devices listed above are substantially equivalent to the predicate devices.