5. 510(k) Summary

I. SUBMITTER

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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

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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.