June 4, 2024

Eminent Spine, LLC
% Chhavy Tep-Cullison
Regulatory Affairs Specialist
Jalex Medical
27865 Clemens Road, Suite 3
Westlake, Ohio 44145

Re: K240505
Trade/Device Name: Eminent Spine SI Screw System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: OUR
Dated: February 21, 2024
Received: May 13, 2024

Dear Chhavy Tep-Cullison:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

Colin O'Neill, MBE
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240505

Device Name

Eminent Spine SI Screw System

Indications for Use *(Describe)*

The Eminent Spine SI Screw System is intended for sacroiliac joint fusion for conditions including degenerative sacroiliitis and sacroiliac joint disruptions, 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. This includes those whose symptoms began during pregnancy or in the peripartum period and have persisted postpartum for more than 6 months.

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

Submitted By:	Eminent Spine, LLC 2004 Ventura Dr. Suite #100 Plano, TX 75093
Date:	02/21/2024
Contact Person:	Chhavy Tep-Cullison, Regulatory Affairs Specialist
Contact Telephone:	(440) 320-4338
Contact Fax:	(440) 933-7839
Device Trade Name:	Eminent Spine SI Screw System
Device Classification Name:	Smooth or threaded metallic bone fixation fastener (21 CFR 888.3040)
Device Classification:	Class II
Reviewing Panel:	Orthopedic
Product Code:	OUR
Predicate Device:	Entasis 3D Dual-Lead Sacroiliac Implant System (K223708)
Reference Device:	T-FIX® 3DSI Joint Fusion System (K214123)

Device Description:

The Eminent Spine Sacroiliac (SI) Screw System is intended for sacroiliac joint fixation for conditions including degenerative sacroiliitis and sacroiliac joint disruption. The Eminent Spine SI Screw System consists of screws manufactured from Ti-6Al-4V ELI per ASTM F136 using traditional machining methods, as well as 3D-printed titanium alloy Ti-6Al-4V ELI per ASTM F3001. The screws are available in a variety of lengths and diameters to accommodate varying patient anatomy. The cannulated screws have open and porous graft windows for the Ø8.5, Ø10.0, Ø11.5, and Ø13.0mm options to allow bone growth through the implant. Optional locking crowns/locking fangs are included for all of the available screw diameters to aid in conforming to patient anatomy.

Indications for Use:

The Eminent Spine SI Screw System is intended for sacroiliac joint fusion for conditions including degenerative sacroiliitis and sacroiliac joint disruptions, 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. This includes those whose symptoms began during pregnancy or in the peripartum period and have persisted postpartum for more than 6 months.

Summary of Technological Characteristics:

The Eminent Spine SI Screw System and the predicate system both have the same intended use and fundamental scientific technology. A comparison table of the subject device and predicate device technological characteristics is provided in this submission in Section 005_Substantial Equivalence. A condensed comparison table is also presented below. There are no differences in technological characteristics that raise questions of safety and efficacy.

Table 1: Dimensions and Technological Characteristics Comparison

Item	**Subject Device:** **Eminent Spine SI Screw System**	**Predicate Device:** **Entasis 3D Dual-Lead Sacroiliac Implant System (K223708)**	**Comparison**
Classification Name	Smooth or threaded metallic bone fixation fastener	Smooth or threaded metallic bone fixation fastener	Same
Regulation	21 CFR 888.3040	21 CFR 888.3040	Same
Product Code	OUR	OUR, HWC	Same
Indications for Use	The Eminent Spine SI System is intended for sacroiliac joint fusion for conditions including degenerative sacroiliitis and sacroiliac joint disruptions, 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. This includes those whose symptoms began during pregnancy or in the peripartum period and have persisted postpartum for more than 6 months.	The Entasis 3D Dual-Lead Sacroiliac Implant System is intended for sacroiliac joint fusion for conditions including degenerative sacroiliitis and sacroiliac joint disruptions, 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. This includes those whose symptoms began during pregnancy or in the peripartum period and have persisted postpartum for more than 6 months.	Same
Screw Lengths	20 – 90 mm in 5 mm increments	Machined: 30-70mm in 5mm increments 3D-Printed: 30-110mm in 5mm increments	Substantially Equivalent
Screw Diameters	Ø8.5, Ø10.0, Ø11.5, Ø13.0 mm	Machined: Ø7.0, Ø9.5, Ø11.5mm 3D-Printed: Ø9.5, Ø11.5, Ø14.5mm	Substantially Equivalent
Material	Ti-6Al-4V ELI per ASTM F136 Ti-6Al-4V per ASTM F3001	Ti-6Al-4V ELI per ASTM F136 Ti-6Al-4V per ASTM F3001	Same

Non-Clinical Testing:

Substantial equivalence is supported by the results of mechanical testing which includes static torsion, driving torque, and axial pullout testing per ASTM F3574, and static and dynamic cantilever bend testing per ASTM F3574. Results support that the strength of the subject SI Screw System is sufficient for its intended use and is substantially equivalent to legally marketed predicate devices.

Conclusion:

Based on the indications for use, technological characteristics, and comparison with the predicate device, the subject device has demonstrated substantial equivalence.