October 7, 2025

Eminent Spine, LLC
Stephen Courtney
Chief Executive Officer
2004 Ventura Dr.
Ste 100
Plano, Texas 75093

Re: K250894
Trade/Device Name: Eminent Spine Posterior SI System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: OUR
Dated: September 5, 2025
Received: September 5, 2025

Dear Stephen Courtney:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

MAZIAR SHAH-MOHAMMADI -S

[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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K250894

Please provide the device trade name(s).

Eminent Spine Posterior SI System

Please provide your Indications for Use below.

The Eminent Spine Posterior 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. This includes those whose symptoms began during pregnancy or in the peripartum period and have persisted postpartum for more than 6 months.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

Submitted By:	Eminent Spine, LLC 2004 Ventura Dr. Suite #100 Plano, TX 75093
Date:	3/24/2025
Contact Person:	Stephen Courtney, CEO, Eminent Spine
Contact Telephone:	972-499-3593
Device Trade Name:	Eminent Spine Posterior SI System
Device Classification Name:	Smooth or threaded metallic bone fixation fastener (21 CFR 888.3040)
Device Classification:	Class II
Reviewing Panel: Product Code:	Orthopedic OUR
Primary Predicate:	Ilion Medical NADIA SI Fusion System (K190580)
Additional Predicate:	Omnia Medical PsiF DNA™ System (K242431)
Additional Predicate:	Eminent Spine SI Screw System (K240505)
Reference Device:	Synthes 6.5mm Cannulated Screw (K021932)

Device Description:

The Eminent Spine Posterior SI System is inserted through an SI posterior approach and packed with autogenous bone graft to facilitate fusion. There are teeth on the superior and inferior surfaces of the device to inhibit movement of the device and to aid in expulsion resistance, while screws are inserted through the anterior face of the implant for bone fixation, adding compression and transfixation in the SI joint. The device is intended to provide mechanical support to the implanted level until fusion is achieved.

The cages are made from additively manufactured Ti-6Al-4V per ASTM F3001. The integrated fixation screws and screw anti-backout plate are manufactured from Ti-6Al-4V ELI per ASTM F136.

The SI posterior system cages are available in one footprint with a lordotic angle. The anterior face of the cage has one screw anti-backout plate that rotates to cover the screw heads and prevent the screws from backing out of the cage after insertion. The screws are available in two diameters (Ø3.50mm, Ø3.75mm), in lengths ranging from 10-18 mm. The screws are positioned to span and compress the cortices of the ilium and sacrum of the SI joint.

Indications for Use:

The Eminent Spine Posterior 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. 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 Posterior SI System and the predicate systems have the same intended use and fundamental scientific technology. The subject device was demonstrated to be substantially equivalent to the predicates with respect to indications for use, design, materials, and performance.

Non-Clinical Testing:

Substantial equivalence is supported by the results of mechanical testing according to ASTM F3574-22: Static Shear and Dynamic Shear. Results support that the strength of the subject Posterior SI System is sufficient for its intended use and is substantially equivalent to legally marketed predicate devices. Substantial equivalence is also supported by the results of cadaveric testing. Testing methods, data, and reports are provided in this submission.

Conclusion:

Based on the indications for use, technological characteristics, and comparison with the predicate device, the subject device has demonstrated substantial equivalence to the legally marketed predicates