January 20, 2023

Aegis Spine, Inc.
Kihyang Kim
RA
9781 S. Meridian Blvd, Ste 300
Englewood, Colorado 80112

Re: K223521
Trade/Device Name: ZESPIN SI 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: November 20, 2022
Received: November 23, 2022

Dear Kihyang Kim:

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,

Colin O'neill -S

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)*

K223521

Device Name

ZESPIN SI Joint Fusion System

Indications for Use *(Describe)*

The ZESPIN SI Joint Fusion System is intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.

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

The following 510(k) summary is being submitted as required by 21 CFR 807.92(a):

1. MANUFACTURER

Submitter's Name:	Aegis Spine, INC.
Submitter's Address:	9781 S. Meridian Blvd, Ste 300 Englewood, CO 80112
Submitter's Telephone:	+1.303.741.4123
Contact Person:	Kihyang Kim +1.303.741.4123 khkim@aegisspine.com/khkim3747@gmail.com

2. DEVICE IDENTIFICATION

Device Trade Name	ZESPIN SI Joint Fusion System
Common/Usual Name	Sacroiliac joint fixation, Bone Screw
Regulation Class /Number	Class II / 21 CFR 888.3040
Regulation Name	Smooth or threaded metallic bone fixation fastener
Product Code	OUR
Classification Panel	Spinal Devices (DHT6B)

3. PREDICATE OR LEGALLY MARKETED DEVICES WHICH ARE SUBSTANTIALLY EQUIVALENT.

The subject devices are similar to the predicate devices in all characteristics.

Subject Device Name	510K NO.	Trade or Proprietary or Model Name	Predicate Type
ZESPIN SI Joint Fusion System	K 210035	ZESPIN SI Joint Fusion System	Primary
	K 152237	Entasis™ Dual-Lead Sacroiliac Implant	Additional

The design feature, indications for use and manufacturing process for the subject devices are substantially equivalent to the predicate devices.

4. MATERIALS

ZESPIN SI Joint Fusion System	Ti-6Al-4V ELI titanium alloy (ASTM F136)

And the additional components material is the same material used in the predicate devices (K 210035).

5. DESCRIPTION OF THE DEVICE

The ZESPIN SI Joint Fusion System consists of different diameter bone screws in various lengths and thread configurations to accommodate variations in patient anatomy. The devices are manufactured from titanium alloy per ASTM F136. The subject submission introduces additional designs and sizes of the arch screw and locking screw.

- Arch Screw will be implanted in patient's bone then autograft will be inserted.
- Locking Screw can be used with washer or can be used on its own
- Self-tapping flute centers screw for easy insertion

6. INDICATION FOR USE

The ZESPIN SI Joint Fusion System is intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.

7. PERFORMANCE TESTING

ZESPIN SI Joint Fusion System

A risk assessment, including FE analysis, was conducted to confirm that the additional components do not introduce new issues of safety or effectiveness. The risk assessment confirmed that none of the additional components is the worst case of the ZESPIN SI Joint Fusion System and the additional components added through this submission do not require additional mechanical testing.

Therefore, we substitute mechanical test data of ZESPIN SI Joint Fusion System for additional components with the predicate device data (K210035).

8. SUMMARY OF TECHNOLOGY CHARACTERISTICS

Subject devices are similar to the predicate devices in all (Material, Indication for use, Design, Manufacturing process, Surgical approach) characteristics

9. SUBSTANTIAL EQUIVALENCE

Subject devices are substantially equivalent to the predicate devices in indications for use, design, function and materials used.

10. CONCLUSION

The overall technology characteristics lead to the conclusion that the ZESPIN SI Joint Fusion System is substantially equivalent to the predicate devices(K210035).