



July 28, 2023

Alevio, LLC
% Nathan Wright
Engineer & Regulatory Specialist
Empirical Technologies
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K231951

Trade/Device Name: SI-Cure Sacroiliac 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: June 30, 2023
Received: June 30, 2023

Dear Nathan Wright:

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

Indications for Use

Submission Number (if known)

K231951

Device Name

SI-Cure Sacroiliac Joint Fusion System

Indications for Use (Describe)

The SI-Cure Sacroiliac Joint Fusion System is intended for sacroiliac fusion for the following conditions:

- Sacroiliac joint dysfunction that is a direct result of sacroiliac joint disruption and degenerative sacroiliitis. This includes conditions whose symptoms began during pregnancy or in the peripartum period and have persisted postpartum for more than 6 months.
- To augment immobilization and stabilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion.
- 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) SUMMARY

Submitter's Name:	Alevio, LLC
Submitter's Address:	200 Cahaba Park Circle Suite 100 Birmingham, Alabama 35242
Submitter's Telephone:	205-783-5778
Contact Person:	Nathan Wright MS, RAC Empirical Technologies 719-351-0248 nwright@empiricaltech.com
Date Summary was Prepared:	June 30, 2023
Trade or Proprietary Name:	SI-Cure Sacroiliac Fusion Joint System
Device Classification Name:	Smooth or Threaded Metallic Bone Fixation Fastener
Classification & Regulation #:	Class II per 21 CFR §888.3040
Product Code:	OUR
Classification Panel:	Orthopedic Devices – Spinal Devices (DHT6B)



DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The SI-Cure Sacroiliac Joint Fusion System consists of titanium bone screws of Ø7 mm, Ø8.5 mm, Ø9.5 mm, Ø10.5 mm, and Ø11 mm diameter and various lengths to accommodate patient anatomy. An optional serrated washer can be placed on the screw head for load distribution. The screws are made from titanium alloy Ti-6AL-4V ELI per ASTM F136.

The purpose of this submission is to add headless screws with additional screw size options to the previously cleared system.

INDICATIONS FOR USE

The SI-Cure Sacroiliac Joint Fusion System is intended for sacroiliac fusion for the following conditions:

- Sacroiliac joint dysfunction that is a direct result of sacroiliac joint disruption and degenerative sacroiliitis. This includes conditions whose symptoms began during pregnancy or in the peripartum period and have persisted postpartum for more than 6 months.
- To augment immobilization and stabilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion.
- Acute, non-acute, and non-traumatic fractures involving the sacroiliac joint.

TECHNOLOGICAL CHARACTERISTICS

The subject and predicate devices have nearly identical technological characteristics and the minor differences do not raise any new issues of safety and effectiveness. Specifically, the following characteristics are similar or the same between the subject and predicates:

- Indications for Use
- Material of Manufacture
- Structural Support Mechanism
- Sizes and Features

- Sterilization
- Manufacturing and Biocompatibility
- Mechanical Performance

Predicate Devices

510k Number	Trade or Proprietary or Model Name	Manufacturer	Predicate Type
K223819	SI-Cure Sacroiliac Fusion Joint System	Alevio, LLC	Primary
K021932	Synthes 6.5 mm Cannulated Screws	Synthes (USA)	Additional

PERFORMANCE DATA

Bench testing was not required in this submission because the addition of the headless screws and length and diameter options do not introduce a new worst case for mechanical performance compared to the cleared implants and do not require performance testing.

CONCLUSION

The overall technology characteristics and mechanical performance evaluation lead to the conclusion that subject SI-Cure Sacroiliac Fusion Joint System is substantially equivalent to the predicate device.
