



Spinus International, Inc.  
% Nathan Wright  
Engineer & Regulatory Specialist  
Empirical Testing Corp.  
4628 Northpark Drive  
Colorado Springs, Colorado 80918

March 23, 2021

Re: K203780

Trade/Device Name: Harvester SI: Sacroiliac Fixation System  
Regulation Number: 21 CFR 888.3040  
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener  
Regulatory Class: Class II  
Product Code: OUR  
Dated: January 26, 2021  
Received: January 27, 2021

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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**

510(k) Number (if known)  
K203780

Device Name

**Harvester SI: Sacroiliac Fixation System**

Indications for Use (Describe)

The Harvester SI Fusion System is intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions 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.

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  
[PRASStaff@fda.hhs.gov](mailto:PRASStaff@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:	Spinus International, Inc.
Submitter's Address:	7200 North Interstate Highway 35 Building 1, Suite 101 Georgetown, TX 78626
Submitter's Telephone:	254-760-4173
Contact Person:	Nathan Wright MS Empirical Testing Corp. 719-351-0248 <a href="mailto:nwright@empiricaltech.com">nwright@empiricaltech.com</a>
Date Summary was Prepared:	December 23, 2020
Trade or Proprietary Name:	Harvester SI: Sacroiliac Fixation System
Common or Usual Name:	Sacroiliac Joint Fixation
Classification:	Class II per 21 CFR §888.3040
Product Code:	OUR
Classification Panel:	Orthopedic

### DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Harvester SI: Sacroiliac Fixation System (also called Harvest SI Sacroiliac Joint Fusion System and Harvester SI Fusion System) is comprised of threaded fusion implants for coupling and fusing the ilium to the sacrum (sacroiliac fusion). The goal of the fusion arthrodesis is to immobilize the sacroiliac joint with two (2) or more threaded implants. The procedure may or may not be bilateral. The Harvester SI System Fusion implants are manufactured from titanium alloy (Ti-6Al-4V ELI) per ASTM F136. The Harvester SI Fusion System is offered in various diameters and lengths to accommodate patient anatomy. Instruments are provided that facilitate the insertion of the implants.

### INDICATIONS FOR USE

The Harvester SI Fusion System is intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions 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.

### 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 identical between the subject and predicates:

- Indications for Use
- Materials of manufacture
- Structural support mechanism

- Sizes
- Surgical approach

Table 5-1 Predicate Devices

<b>510k Number</b>	<b>Trade or Proprietary or Model Name</b>	<b>Manufacturer</b>	<b>Predicate Type</b>
K152237	Entasis™ Dual-Lead Sacroiliac Implant	CoreLink	Primary
K121148	SAMBA™ Screw System	Medical Designs LLC	Additional
K183342	SambaScrew 3D SI Fusion System	Orthofix Inc.	Additional
K201538	Life Spine SIMPACT Sacroiliac Joint Fixation System	Life Spine Inc.	Additional
K161210	Rialto™ SI Fusion System	Medtronic Sofamor Danek	Additional

#### PERFORMANCE DATA

The Harvester SI: Sacroiliac Fixation System has been tested in the following test modes:

- Axial pullout per ASTM F543
- Torsional properties per ASTM F543
- Static cantilever bending per ASTM F2193
- Dynamic cantilever bending per ASTM F2193

The results of this non-clinical testing show that the strength of the Harvester SI: Sacroiliac Fixation System is sufficient for its intended use and is substantially equivalent to legally marketed predicate devices.

#### CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that the Harvester SI: Sacroiliac Fixation System is substantially equivalent to the predicate device.