OsteoCentric Technologies
℅ Roshana Ahmed
Sr Regulatory Specialist
Telos Partners LLC
2458 Frontier Drive
Warsaw, Indiana 46582

September 21, 2023

Re: K230226
Trade/Device Name: Integrity-SI® 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: August 25, 2023
Received: August 25, 2023

Dear Roshana Ahmed:

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,

Eileen Cadel -S

Digitally signed by Eileen Cadel -S
Date: 2023.09.21 14:59:18 -04'00'

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

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)*
K230226

Device Name

Integrity-SI® Fusion System

Indications for Use *(Describe)*

The Integrity-SI Fusion System is intended for sacroiliac joint 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.

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510(k) Summary

I. Submitter

OsteoCentric Technologies
75 West 300 N, Suite 150
Logan, UT 84321
Phone: 1-800-969-0639

Submitter Contact Person: Todd Evans, Senior Director of Quality and Regulatory Affairs
Submission Contact Person: Roshana Ahmed, M.A., RAC, Sr. Regulatory Specialist

Date Prepared: September 19, 2023

II. Device

Device Proprietary Name:	Integrity-SI® Fusion System
Common or Usual Name:	Sacroiliac Joint Fixation
Classification Name:	Smooth or threaded metallic bone fixation fastener
Regulation Number:	21 CFR 888.3040
Product Code:	OUR
Device Classification	Class II

III. Predicate Device

Primary predicate:

- Integrity-SI® Fusion System, K222512, OsteoCentric Technologies

Additional predicates:

- CoorsTek Integrity-SI Fusion System, K161755, CoorsTek Medical, LLC
- Cannulated Fasteners and Nuts, K211290, OsteoCentric Technologies
- Synthes 6.5 mm Cannulated Screw, K021932, Synthes (USA)
- SI-Cure Sacroiliac Joint Fusion System, K231951, Alevio, LLC

IV. Device Description

The Integrity-SI® Fusion System consists of partially and fully threaded, self-tapping cannulated titanium implants designed to be inserted across sacroiliac joint providing stability for joint arthrodesis when used in conjunction with allograft or autograft. The surgical implants are available in various sizes to accommodate patient anatomy. The 8 mm, 10 mm, and 12 mm diameter screws are offered in partially and fully threaded version in lengths from 40 – 110 mm, in 2.5 mm increments and are available in non-coated or hydroxyapatite-coated (HA) versions. The screws also include a pre-assembled washer for improved joint compression. The fully

threaded 6.5 mm diameter, optional, secondary fasteners are offered for additional rotational stability in lengths of 30 – 70 mm, in 5 mm increments and are only intended for use in conjunction with a primary 8 mm, 10 mm, or 12 mm screw.

The screws are provided in sterile and non-sterile options.

V. Indications for Use

The Integrity-SI Fusion System is intended for sacroiliac joint 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.

VI. Comparison of Technological Characteristics to the Predicate

There are no changes to the Indications for Use statement.

The subject device is identical to the predicate device with respect to materials of construction, sterilization, and manufacturing methods. The only difference between the subject and predicate device is introduction of the 8 mm fastener, introduction of additional fastener sizes in 2.5 mm increments, addition of non-sterile fasteners to the product line, and the addition of new instruments (5.0 mm drill, taps, and new depth gauge).

VII. Performance Data

Mechanical testing of the subject device was undertaken in accordance with ASTM F543-17 to demonstrate substantial equivalence. The following tests were performed:

- Torsional properties per ASTM F543-17
- Driving and removal torque per ASTM F543-17
- Axial pullout per ASTM F543-17

In addition, this submission leverages verification and validation testing previously submitted by the applicant under K161755 and K210754.

VIII. Conclusion

As noted above, the only difference between the predicate and subject device is the introduction of an 8 mm screw and new instruments. This difference does not raise any new questions of safety and efficacy and is supported by the information provided in this submission. Therefore, the Integrity-SI® Fusion System is substantially equivalent to the predicate device.