September 12, 2022

OsteoCentric Technologies
% Mr. Ken Riordan
Regulatory Project Manager
Telos Partners, LLC
2850 Frontier Drive
Warsaw, Indiana 46582

Re: K222512
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 17, 2022
Received: August 19, 2022

Dear Mr. Riordan:

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, 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)*

K222512

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:

1.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.

2. To augment immobilization and stabilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion.

3. 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.

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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: Ken Riordan, Regulatory Project Manager, Telos Partners, LLC

Date Prepared: August 11, 2022

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

Substantial equivalence is claimed to the following devices:

- CoorsTek Integrity-SI Fusion System, K161755 (Primary Predicate)
- SI-BONE iFuse Implant System, K193524

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 10mm and 12mm diameter screws are offered in partially and fully threaded version in lengths from 40-110mm, in 5mm increments. All fastener sizes are available in non-coated or hydroxyapatite-coated (HA) versions. The 10mm and 12mm screws also include a pre-assembled washer for improved joint compression. The fully threaded 6.5mm diameter, optional secondary fasteners are offered for additional rotational stability in lengths of 30 – 70 mm, in 5mm increments and are only intended for use in conjunction with a primary 10mm or 12mm screw.

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 technological characteristics of the OsteoCentric Integrity-SI Fusion System. The device is identical to the predicate device with respect to the design, materials, sterilization, and manufacturing methods. The change to the Indications for Use does not change the intended use of the device, does not introduce new indications, and does not change the therapeutic effect or use of the implants.

VII. Performance Data

There were no changes in the design, materials, sterilization, or manufacturing methods of the device. Therefore, no new performance data was required to demonstrate the substantial equivalence of the subject device to the predicate device.

VIII. Conclusion

The technological characteristics and intended use have not changed compared to the predicate device. Therefore, the OsteoCentric Integrity-SI Fusion System is substantially equivalent to the predicate device.