DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

December 14, 2016

CoorsTek Medical LLC
Mr. Steve Brown
QA/RA Manager
560 West Golf Course Road
Providence, Utah 84332

Re: K161755
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: November 17, 2016
Received: November 18, 2016

Dear Mr. Steve Brown:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161755

Device Name
Integrity-SI Fusion System

Indications for Use *(Describe)*
The Integrity-SI Fusion System device 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.

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Section 4: 510(k) SUMMARY [As required by 21 CFR 807.92 (c)]

Submitter / Contact Person / Date of Preparation

Submitter/Sponsor	CoorsTek Medical LLC 560 W. Golf Course Rd. Providence, UT 84332 Phone: 435-774-1535 Fax: 435-753-7698
Contact Person	Steve Brown
Date of preparation	December 9th, 2016

General Information

Trade Name	Integrity-SI™ Fusion System
Common / Usual Name	Sacroiliac Joint Fixation - Smooth or threaded metallic bone fixation fastener
Classification Name and Number	Sacroiliac Joint Fixation, 888. 3040
Regulatory Class	Class II
Device Regulation Panel	Orthopedics
Product Code	OUR
Manufacturer	CoorsTek Medical LLC 560 W. Golf Course Rd. Providence, UT 84332
Identification of Legally Marketed Predicate Devices	• Synthes 6.5 mm Cannulated Screw (K021932) • Zyga Technology SImmetry® Sacroiliac Joint Fusion System (K141549) • Medtronic Sofamor Danek MSB Sacroiliac Joint Fusion Device (K110472)

Device Description	The Integrity-SI™ Fusion System consists of partially and fully threaded, self-tapping cannulated titanium (Ti-6Al-4V ELI per ASTM F136) implants designed to be inserted across sacroiliac joint to provide stability for joint arthrodesis. The surgical implants are available in various sizes to accommodate patient anatomy. The 10mm and 12mm diameter screws are offered in and partially and fully threaded versions in lengths ranging from 40-110mm, in 5mm increments. All screw 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 screws are offered from lengths of 30 – 70 mm, in 5mm increments. All implants are provided sterile and are individually packaged. The 6.5 mm screws are not for use without the subject 10 mm or 12 mm screws.
Intended Use	The system is used to provide structural stability in skeletally mature individuals who have developed a clinical need to alleviate chronic pain due to SI joint disruptions and degenerative sacroiliitis.
Indications for Use	Integrity-SI™ Fusion System is intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroilitis.
Indications for Use Comparison	The intended use for the subject and predicate devices are the same. The indications for use statement for the subject device and the Zyga Technology SImmetry (K021932) and Medtronic Sofamor Danek MSB Sacroiliac Joint Fusion Device (K110472) predicates are identical. The Synthes 6.5 mm Cannulated Screw (K021932) indications for use statement is broader than the subject device but does include *SI joint disruption*s.

Summary of Non-Clinical Performance Data	Testing was performed for the Integrity-SI™ Fusion System and demonstrated substantially equivalent performance to the identified predicates. The following mechanical tests were performed: • Torsional strength/breaking angle (ASTM F543-13e1) • Insertion/removal torque (ASTM F543-13e1) • Pullout force (ASTM F543-13e1) • Static Bending Strength (ASTM F2193-14) • Fatigue Bending Strength (ASTM F2193-14) Tests completed for insertion torque and axial pullout strength demonstrate the subject devices are substantially equivalent with respect to mechanical performance of the K021932 predicate device. Additionally, testing for torque to failure, mean bending yield strength and bending fatigue life provide evidence the device is capable of withstanding expected loading without failure. Cadaveric testing demonstrates the subject device can be safely implanted using the surgical technique.
Technological Characteristics Comparison	The technological characteristics and intended use of the subject devices is identical to that of the predicate devices cleared under the following submissions: • K141559 Slmmetry Sacroiliac Joint Fusion System • K110472 Medtronic Sacroiliac Fusion Device • K021932 Synthes 6.5mm Cannulated Screw Both subject and predicate devices include titanium alloy bone screws that are inserted across the SI joint to provide a stable construct to promote arthrodesis across the joint. As a result, the subject device does not introduce any new concerns of safety or effectiveness.
Conclusion	Based upon a comparison of the design features, indications for use, technological characteristics, the use of established well known materials, and mechanical performance, the Integrity-SI™ Fusion System has demonstrated substantial equivalence to the identified predicate device systems. The performance data demonstrates that the devices included in the Integrity-SI™ Fusion System do not raise any new questions of safety or effectiveness.