October 3, 2018

SIJ Surgical
% Meredith L. May, MS, RAC
Partnership Manager
Empirical Consulting, LLC
4628 Northpark Drive
Colorado Springs, Colorado 80918

Re: K181881
Trade/Device Name: Outlet 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: July 12, 2018
Received: July 13, 2018

Dear Ms. May:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ronald P. Jean -S

for 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181881

Device Name
Outlet Sacroiliac Joint Fusion System

Indications for Use *(Describe)*

The Outlet Sacroiliac Joint Fusion System 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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5. 510(K) SUMMARY

Submitter's Name:	SIJ Surgical
Submitter's Address:	6829 Falls of Neuse Rd. Suite 103 Raleigh, NC 27615
Submitter's Telephone:	314-494-0313
Contact Person:	Meredith L. May MS, RAC Empirical Consulting 719.337.7579
Date Summary was Prepared:	12 July 2018
Trade or Proprietary Name:	Outlet Sacroiliac Joint Fusion System
Common or Usual Name:	Sacroiliac Joint Fixation
Classification:	Class II per 21 CFR §888.3040 Smooth Or Threaded Metallic Bone Fixation Fastener
Product Code:	OUR
Classification Panel:	Office of Device Evaluation, Division of Orthopedic Devices, Posterior Spine Devices Branch

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Outlet Sacroiliac Joint Fusion System consists of cannulated, fully threaded screws with double helix threads designed to be able to screw into pre-drilled bone. It is fabricated from medical grade titanium alloy, Ti-6Al-4V (ASTM F-136). The Outlet System implants come in various sizes and lengths to accommodate patient anatomy. Optional washers are included for each screw diameter to aid in conforming to patient anatomy.

INDICATIONS FOR USE

The Outlet Sacroiliac Joint Fusion System is intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.

The indications for use for the Outlet Sacroiliac Joint Fusion System is similar to that of the predicate devices.

TECHNOLOGICAL CHARACTERISTICS

The Outlet Sacroiliac Joint Fusion System consists of cannulated, fully threaded screws with double helix threads designed to be able to screw into pre-drilled bone. It is fabricated from medical grade titanium alloy, Ti-6Al-4V (ASTM F-136). The screws are offered in 11 and 13mm diameters with lengths ranging from 30 – 80mm to accommodate patient anatomy. Optional washers are included for each screw diameter to aid in conforming to patient anatomy.

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
- Physical Characteristics
- Surgical Site/Approach
- Material
- Sterility

Table 5-1 Predicate Devices

510k Number	**Trade or Proprietary or Model Name**	**Manufacturer**	**Predicate Type**
K021932	6.5mm Cannulated Screw	Synthes	Primary
K110472	MSB Sacroiliac Joint Fusion System	Medtronic Sofamor Danek, Inc	Additional
K112028	SI-LOK Sacroiliac Joint Fixation System	Globus Medical, Inc	Additional
K141549	SImmetry Sacroiliac Joint Fusion System	Zyga Technology, Inc.	Additional

PERFORMANCE DATA

Bench testing has been conducted to establish performance to design requirements and specification and to support the substantial equivalence of the device. The Outlet Sacroiliac Joint Fusion System was mechanically characterized with the following tests:

- Static Three-point bending per ASTM F2193-14
- Dynamic Three-point bending per ASTM F2193-14
- Static Torsion per ASTM F543-13
- Screw Axial Pullout per ASTM A543-13
- Static Driving Torque per ASTM A543-13

The results of this non-clinical testing show that the strength of the Outlet Sacroiliac Joint Fusion System is substantially equivalent to legally marketed predicate devices.

CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that the Outlet Sacroiliac Joint Fusion System is substantially equivalent to the predicate device.