September 26, 2019

Genesys Spine
Mr. William W. Sowers
VP of Engineering
1250 Capital of Texas Highway South, Building Three, Suite 600
Austin, Texas 78746

Re: K191748
Trade/Device Name: Genesys Spine 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: June 28, 2019
Received: July 1, 2019

Dear Mr. Sowers:

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,

Ronald P. Jean, Ph.D.
Director (Acting)
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

3. INDICATIONS FOR USE STATEMENT

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)*

K191748

Device Name
Genesys Spine Sacroiliac Joint Fusion System

Indications for Use *(Describe)*
The Genesys Spine Sacroiliac Joint Fusion System is intended for sacroiliac joint fusion for conditions including degenerative sacroiliitis and sacroiliac joint disruptions.

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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"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."

4. 510(K) SUMMARY

Submitter's Name:	Genesys Spine
Submitter's Address:	1250 Capital of Texas Highway South Building Three, Suite 600 Austin, Texas 78746
Contact Name:	William W. Sowers
Submitter's Telephone:	512-381-7080
Submitter's Fax:	512-381-7076
Date Summary was Prepared:	June 28, 2019
Trade or Proprietary Name:	Genesys Spine Sacroiliac Joint Fusion System
Common or Usual Name:	Sacroiliac Joint Fixation
Classification Name:	Smooth or Threaded Metallic Bone Fixation Fastener
Classification:	Class II
Regulation Number:	21 CFR §888.3040
Product Codes:	OUR
Classification Panel:	Orthopedic Devices (OHT6), Spine Devices (DHT6B)
Legally Marketed (unmodified) devices to Which Substantial Equivalence is Claimed:	Primary Predicate: Silex Sacroiliac Joint Fusion System (X-Spine Systems, Inc. – K123702) Additional Predicates: Synthes 6.5mm Cannulated Screw (Synthes (USA) – K021932) SI Joint Fusion System (SI-Bone, Inc. – K080398 & K092375) SImmetry Sacroiliac Joint Fusion System (Zyga Technology, Inc. – K141549) RIALTO SI Fusion System (Medtronic Sofamor Danek – K161210)

DEVICE DESCRIPTION:

Genesys Spine's Sacroiliac Joint Fusion System consists of partially threaded and fully threaded implants designed to secure the sacroiliac joint and minimize micromotion in order to enable bony fusion. All screws and anchors are cannulated and self-tapping; they are offered with different diameters (up to 13.5mm), lengths (up to 70mm), and styles to accommodate variations in patient anatomy and surgeon preference.

Fusion across the graft space can be aided by the addition of bone graft material to the lumen of each screw; fenestration in each screw allow for direct allograft apposition across the sacroiliac joint. Dual thread screws and fully threaded screws provide joint compression by utilizing a compressive thread

pattern. Optional Washers are included to aid in conforming to patient anatomy and to help distribute the load onto a larger area. All implants are fabricated from medical grade titanium alloy (Ti-6Al-4V ELI).

The delivery system uses guide pins for accurate surgical placement into pre-drilled bone. All implants will be provided non-sterile and are intended for single use only.

INDICATIONS FOR USE

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

TECHNOLOGICAL COMPARISON TO PREDICATES

The Genesys Spine Sacroiliac Joint Fusion System is substantially equivalent to the predicate systems in terms of:

- Indications for Use
- Physical Characteristics
- Mechanical Performance
- Principals of Operation
- Surgical Approach
- Materials
- Sterility

As a result, the subject device does not introduce any new concerns of safety or effectiveness.

NON-CLINICAL PERFORMANCE EVALUATION

Nonclinical testing was performed on worst-case devices for the Genesys Spine Sacroiliac Joint Fusion System and demonstrated substantially equivalent performance to the predicate systems. The following mechanical tests were performed:

- Static Bending Strength (ASTM F2193-18a)
- Fatigue Bending Strength (ASTM F2193-18a)
- Torsional strength/breaking angle (ASTM F543-17)
- Insertion/removal torque (ASTM F543-17)
- Pullout force (ASTM F543-17)

CONCLUSION

There are no significant differences between the Genesys Spine Sacroiliac Joint Fusion System and other systems currently being marketed which would adversely affect the use of the product. It is substantially equivalent in design, material, features, function, and intended use.