March 29, 2024

Genesys Spine
Derek Southard
Chief Technical Officer
1250 S. Capital of Texas Highway Building 3, Suite 600
Austin, Texas 78746

Re: K233595
Trade/Device Name: Genesys Spine Sacroiliac Joint Fusion System with Navigation
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: February 28, 2024
Received: February 28, 2024

Dear Derek Southard:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Shumaya Ali -S

Shumaya Ali, MPH
Assistant Director
DHT6C: Division of Restorative, Repair and Trauma 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.*

Submission Number *(if known)*

K233595

Device Name

Genesys Spine Sacroiliac Joint Fusion System with Navigation

Indications for Use *(Describe)*

The Genesys Spine Sacroiliac Joint Fusion System with Navigation is intended to be used with the Genesys Spine Sacroiliac Joint Fusion System to assist the surgeon in precisely locating anatomical structures in SIros and SIros O procedures, in which the use of stereotactic surgery may be appropriate, and where reference to anatomical structures, such as the pelvis or vertebra, can be identified relative to acquired imaging (CT, MR, 2D fluoroscopic image or 3D fluoroscopic image reconstruction) and/or image data based models of the anatomy. Navigation instruments are intended to be used with the Medtronic O-arm® Imaging System and StealthStation® Navigation System.

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

Prepared on: 2023-11-08

## Contact Details

21 CFR 807.92(a)(1)

| | |
|---|---|
| Applicant Name | Genesys Spine |
| Applicant Address | 1250 S. Capital of Texas Highway Building 3, Suite 600 Austin TX 78746 United States |
| Applicant Contact Telephone | 512-381-7080 |
| Applicant Contact | Mr. Southard Derek |
| Applicant Contact Email | derek.southard@genesysspine.com |

## Device Name

21 CFR 807.92(a)(2)

| | |
|---|---|
| Device Trade Name | Genesys Spine Sacroiliac Joint Fusion System with Navigation |
| Common Name | Stereotaxic instrument |
| Classification Name | Orthopedic Stereotaxic Instrument |
| Regulation Number | 882.4560 |
| Product Code | OLO |

## Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

| Predicate # | Predicate Trade Name (Primary Predicate is listed first) | Product Code |
|---|---|---|
| K172268 | iFuse Implant System - iFuse Navigation | OLO |
| K191748 | Genesys Spine Sacroiliac Joint Fusion System | OUR |
| K161210 | Medtronic Navigated Manual Reusable Instruments for use with th | OLO |
| K150216 | Medtronic Navigated StealthStation System with Synergy Cranial | HAW |

## Device Description Summary

21 CFR 807.92(a)(4)

GENERAL OVERVIEW
The Genesys Spine Sacroiliac Joint Fusion System with Navigation consist of instruments compatible with the Medtronic O-arm® Imaging System and StealthStation™ Navigation System to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. The Medtronic O-arm® Imaging System and StealthStation™ Navigation System is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the spine or pelvis, can be identified relative to images of the anatomy.

The Genesys Spine Sacroiliac Joint Fusion System consists of implants designed to secure the sacroiliac joint and minimize micromotion to enable bony fusion. All Implants are cannulated and self-tapping; they are offered with different diameters and lengths to accommodate variations in patient anatomy and surgeon preference. The SIros® and SIros OTM Sacroiliac Joint Fusion System implants are manufactured from implant grade titanium (Ti-6AL-4V ELI).

PRODUCT SPECIFICATIONS AND DIMENSIONS
Product and engineering specifications, and engineering drawings for all system specific instruments are provided as attached.

SURGICAL TECHNIQUE
A detailed surgical technique is available as attached. The surgical technique defines the surgical technique for instrumentation use, anatomical location of use, various user interfaces, how the devices interact with other devices, and how the devices interact with the patient.

## Intended Use/Indications for Use 21 CFR 807.92(a)(5)

The Genesys Spine Sacroiliac Joint Fusion System with Navigation is intended to be used with the Genesys Spine Sacroiliac Joint Fusion System to assist the surgeon in precisely locating anatomical structures in SIros and SIros O procedures, in which the use of stereotactic surgery may be appropriate, and where reference to anatomical structures, such as the pelvis or vertebra, can be identified relative to acquired imaging (CT, MR, 2D fluoroscopic image or 3D fluoroscopic image reconstruction) and/or image data based models of the anatomy. Navigation instruments are intended to be used with the Medtronic O-arm® Imaging System and StealthStation® Navigation System.

## Indications for Use Comparison 21 CFR 807.92(a)(5)

The Genesys Spine Sacroiliac Joint Fusion System with Navigation instruments are intended to be used with the Genesys Spine Sacroiliac Joint Fusion System (implants and existing instruments). The Navigation instruments are designed to interface with the already-cleared Medtronic StealthStation® Navigation System to assist surgeons in precisely locating anatomical structures for placement of Genesys Spine SI Joint Fusion implants. These instruments have similar designs as the predicate instruments and incorporate the additional design features based on the predicate and reference devices to enable navigation and use with the StealthStation NavLock trackers.

The Navigation instrument set is intended to be used with the Medtronic StealthStation using the Medtronic O-arm imaging system. The instrument modifications detailed in this submission have no impact on the technological characteristics of either the existing Genesys Spine Sacroiliac Joint Fusion Implant System implants, instruments, or the Medtronic O-arm® and StealthStation® systems.

## Technological Comparison 21 CFR 807.92(a)(6)

The primary predicate device for this 510(k) is the iFuse Implant System - iFuse Navigation (K172268). The Genesys Spine Sacroiliac Joint Fusion System with Navigation is similar to the cited predicate in regard to instrument design, device description, intended use/indications for use, technological characteristics (operating principle, design, materials, manufacturing, etc.) and performance testing.

## Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Testing was completed to ensure the functionality and compatibility with the Medtronic o-arm and StealthStation Systems. The performance testing completed:

1. Registration - Registration testing was performed to ensure that the instruments can be registered to the StealthStation®.
2. Accuracy - Accuracy testing was completed for comparison to the reference instruments.
3. Rigidity - Rigidity testing evaluated the connection between the Medtronic NavLock and the subject instruments.
4. Compatibility with Genesys Spine Sacroiliac Fusion System Implants - Compatibility with the Implant System has been evaluated to ensure that the isubject instruments are compatible with the Implant System.

Not Applicable

The intended use of the subject Genesys Spine Sacroiliac Fusion System with Navigation instruments, as part of the Genesys Spine Sacroiliac Fusion Implant System, is substantially equivalent to the intended use of the predicate instruments. The verification and validation results support substantial equivalence of the subject instruments compared to the predicate and reference devices.