October 22, 2025

Genesys Spine
Bill Sowers
Chief Technical Officer
1250 Capital of Texas Highway South
Building Three, Suite 600
Austin, Texas 78746

Re: K252322
Trade/Device Name: SIros-X System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: OUR, NKB, OLO
Dated: July 25, 2025
Received: July 25, 2025

Dear Bill 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 (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

STEPHANIE SMITH -S

For 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252322

Please provide the device trade name(s).

SIros-X System

Please provide your Indications for Use below.

The SIros-X System is intended for sacroiliac joint fusion in skeletally mature patients 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 patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion.
• Acute, non-acute, and non-traumatic fractures involving the sacroiliac joint.

When connected to the TiLock2 Spinal System, the SIros-X System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to thoracolumbosacral fusion for the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine:

• Degenerative disc disease (DDD) as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies
• Spondylolisthesis
• Trauma (i.e., fracture or dislocation)
• Spinal stenosis
• Deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis)
• Spinal tumor
• Pseudarthrosis
• Failed previous fusion

When connected to the TiLock2 Spinal System, the SIros-X System is intended to provide immobilization and stabilization of spinal segments in skeletally immature patients as an adjunct to thoracolumbar fusion for the treatment of progressive spinal deformities (i.e., scoliosis, kyphosis, or lordosis) including idiopathic scoliosis, neuromuscular scoliosis, and congenital scoliosis, as well as the following conditions: spondylolisthesis/spondylolysis, fracture caused by tumor and/or trauma, pseudarthrosis, and/or failed previous fusion. These devices are to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

The SIros-X Navigation instruments are intended to be used with the SIros-X System to assist the surgeon in precisely locating anatomical structures in SIros-X System procedures, in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the pelvis or vertebra, can be identified relative to the acquired image (CT, MR, 2D fluoroscopic image or 3D fluoroscopic image reconstruction) and/or an image data-based model of the anatomy. The SIros-X Navigation instruments are intended to be used with the Medtronic StealthStation System.

Please select the types of uses (select one or both, as applicable).

☒ Prescription Use (Part 21 CFR 801 Subpart D)
☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) #:

510(k) Summary

Prepared on: 2025-10-21

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Genesys Spine
Applicant Address	1250 Capital of Texas Highway South Building Three, Suite 600 Austin TX 78746 United States
Applicant Contact Telephone	954-557-8288
Applicant Contact	Mr. Bill Sowers
Applicant Contact Email	bill.sowers@Genesysspine.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	SIros-X System
Common Name	Smooth or threaded metallic bone fixation fastener
Classification Name	Sacroiliac Joint Fixation
Regulation Number	888.3040
Product Code(s)	OUR, NKB, OLO

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K233508	iFuse Bedrock Granite® Implant System	OUR
K152039	Genesys Spine TiLock2 Spinal System	NKB
K191748	Genesys Spine Sacroiliac Joint Fusion System	OUR
K233595	Genesys Spine Sacroiliac Joint Fusion System with Navigation	OLO
K021932	Synthes 6.5mm Cannulated Screw	OUR
K153442	CD HORIZON® Spinal System, Medtronic Navigated Manual Reusable Instruments for Use with the STEALTHSTATION® System, Medtronic Reusable Instruments for Use with the IPC® POWEREASE® System, Medtronic Navigated Reusable Instruments for Use with the STEALTHSTATION® and IPC® POWEREASE™ Systems	NKB

Device Description Summary

21 CFR 807.92(a)(4)

The SIros-X System is comprised of cannulated screws of various lengths, diameters, and configurations as well as system specific instruments. Instruments are offered to support open and minimally invasive placement of the SIros-X screws.
The SIros-X System is intended to provide fusion of the sacroiliac joint when multiple SIros-X screws traverse the SI joint. In addition, screws with tulips are intended to provide fixation to the pelvis when used with multi-level pedicle screw constructs that terminate in

the lumbosacral spine.
The SIros-X System navigation instruments are offered to assist the surgeon in precisely locating anatomical structures in SIros-X System procedures in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the pelvis or vertebra, can be identified relative to the acquired image (CT, MR, 2D fluoroscopic image or 3D fluoroscopic image reconstruction) and/or an image data-based model of the anatomy.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The SIros-X System is intended for sacroiliac joint fusion in skeletally mature patients 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 patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion.
• Acute, non-acute, and non-traumatic fractures involving the sacroiliac joint.
When connected to the TiLock2 Spinal System, the SIros-X System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to thoracolumbosacral fusion for the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine:
• Degenerative disc disease (DDD) as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies
• Spondylolisthesis
• Trauma (i.e., fracture or dislocation)
• Spinal stenosis
• Deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis)
• Spinal tumor
• Pseudarthrosis
• Failed previous fusion
When connected to the TiLock2 Spinal System, the SIros-X System is intended to provide immobilization and stabilization of spinal segments in skeletally immature patients as an adjunct to thoracolumbar fusion for the treatment of progressive spinal deformities (i.e., scoliosis, kyphosis, or lordosis) including idiopathic scoliosis, neuromuscular scoliosis, and congenital scoliosis, as well as the following conditions: spondylolisthesis/spondylolysis, fracture caused by tumor and/or trauma, pseudarthrosis, and/or failed previous fusion.
These devices are to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.
The SIros-X Navigation instruments are intended to be used with the SIros-X System to assist the surgeon in precisely locating anatomical structures in SIros-X System procedures, in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the pelvis or vertebra, can be identified relative to the acquired image (CT, MR, 2D fluoroscopic image or 3D fluoroscopic image reconstruction) and/or an image data-based model of the anatomy. The SIros-X Navigation instruments are intended to be used with the Medtronic StealthStation System.

Indications for Use Comparison

21 CFR 807.92(a)(5)

All predicate devices are legally marketed.
The SIros-X System has indications for use that are substantially equivalent to those of the primary predicate
The SIros-X System has technological characteristics that are substantially equivalent to those of the predicates.
All implant sizes, types, materials, manufacturing methods, and characteristics fall within the scope of the predicates. All instruments' designs correlate with existing Genesys Spine instruments and field testing has proven they accurately and reproducibly perform as intended.
The SIros-X System does not raise any new questions regarding safety or efficacy.

Technological Comparison

21 CFR 807.92(a)(6)

The subject device is substantially equivalent to the predicates in terms of intended use, Indications for Use, technological characteristics, materials, manufacturing methods, and principles of operation.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Nonclinical testing was performed on worst-case devices for the SIros-X System and demonstrated substantially equivalent performance to the predicate systems. The following mechanical tests were performed:
• Static & Dynamic Cantilever Bend Testing per ASTM F2193-20 Annex A4
• Static & Dynamic Torsion per ASTM F543-23 Annex A1
• Driving Torque Testing per ASTM F543-23 Annex A2
• Axial Pullout per ASTM F543-23 Annex A3
• Static & Dynamic Axial Compression Bending per ASTM F1717-21

• Static Torsion Testing per ASTM F1717-21
• Navigation Testing
The performance testing was performed in accordance with the applicable portions of Spinal System 510(k)s Guidance Document, dated May 2004.

Genesys Spine's SIros-X System demonstrated strong mechanical performance that was equal to or better than the predicate sacroiliac joint fusion systems and thoracolumbosacral pedicle screw systems.
The SIros-X Navigated Instruments, and compatible implants, are functionally compatible, accurate, and reliable when used in conjunction with the Medtronic StealthStation S8 System and O-Arm.
Based upon the test data and analysis, Genesys Spine's SIros-X System is as safe, as effective, and performs as well or better than the legally marketed predicate Systems.