Life Spine Inc.
Angela Batker
RA/QA Manager
13951 S Quality Drive
Huntley, Illinois 60142

August 19, 2021

Re: K202836
Trade/Device Name: GX Navigation Instrument System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: August 11, 2021
Received: August 13, 2021

Dear Angela Batker:

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,

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

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)*

K202836

Device Name
Gx Navigation Instrument System

Indications for Use *(Describe)*

The GX Navigation Instruments are intended to be used during the preparation and placement of Life Spine screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. These instruments are designed for use with the Medtronic StealthStation System, which 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 vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

The GX Navigation Instruments are compatible with the following Life Spine implant systems:
ARX Spinal System, Avatar Extended Tab MIS System, Nautilus Thoracolumbar Spinal System, Centerline Thoracolumbar Spinal System and Centric-T 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.

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510(k) Summary
GX Navigation Instrument System

Submitted By: Life Spine, Inc.
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Fax: 847-884-6118

510(k) Contact: Angela Batker
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Inc.
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Telephone: 847-884-6117
Fax: 847-884-6118

Date Prepared: June 29th, 2021

Trade Name: GX Navigation Instrument System

Common Name: Stereotaxic Instruments

Classification: CFR 882.4560, Class II, Stereotaxic instrument

Product Code: OLO

Primary Predicate: Medtronic CD Horizon (K170679)

Additional Predicates: Life Spine Avatar/Nautilus & Centerline (K111953, K132760 & K151196)Life Spine ARx Spinal System (K200070 & K191575)

Device Description:

The GX Navigation instruments are manufactured from Stainless Steel as specified in ASTM F899, non-sterile, reusable instruments designed to function with the Medtronic® StealthStation® System. Refer to the appropriate navigation system Instructions for Use and/or Surgical Technique Guide for details regarding navigation system use.

The GX Navigation instruments are for use with systems,

specifically:

ARx Spinal System
- Polyaxial Driver Non-Cannulated
- Polyaxial Driver Cannulated
- Monoaxial Driver Non-Cannulated
- Monoaxial Driver Cannulated
- Reduction Driver Non-Cannulated
- Reduction Driver Cannulated
- Monoaxial Reduction Driver Non-Cannulated
- Monoaxial Reduction Driver Cannulated
- Non-Cannulated Taps

Cannulated Taps* Nautilus Thoracolumbar Spinal System
- Polyaxial Driver Non-Cannulated
- Polyaxial Driver Cannulated
- Centric-T Modular Tap Driver
- Reduction Driver Non-Cannulated
- Reduction Driver Cannulated
- Non-Cannulated Taps
- Cannulated Taps

Avatar Extended Tab MIS System
- MIS Polyaxial Driver
- Non-Cannulated Taps
- Cannulated Taps

Centerline Thoracolumbar Spinal System
- Polyaxial Driver Non-Cannulated
- Polyaxial Driver Cannulated
- Reduction Driver Non-Cannulated
- Reduction Driver Cannulated
- Non-Cannulated Taps
- Cannulated Taps

Centric-T
- Centric-T Modular Tap Driver
- Non-Cannulated Taps
- Cannulated Taps

Indications for Use:
The GX Navigation Instruments are intended to be used during the preparation and placement of LifeSpine screws during spinal surgery to assist the surgeon in precisely locating anatomical structures ineither open or minimally invasive procedures. These

instruments are designed for use with the Medtronic StealthStation System, which 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 vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

The GX Navigation Instruments are compatible with the following Life Spine implant systems: ARx Spinal System, Avatar Extended Tab MIS System, Nautilus Thoracolumbar Spinal System,Centerline Thoracolumbar Spinal System and Centric-T System.

Technological Characteristics:
The GX Navigation System is substantially equivalent to the predicate systems in terms of design, materials, indications for use and sizing.

Material:
This submission seeks clearance of just the GX Navigation Instrument System which are made from Stainless Steel according to F899. This this is the same material used in the predicate devices.

Performance Data:
Testing according to Standard Practice for Measurement of Positional Accuracy of Computer Assisted Surgical Systems testing to ASTM F2554-18 was presented to demonstrate substantial equivalency to the Medtronic CD HORIZON® Spinal System (K170679). Additionally, design validation, including dimensional comparison and tolerance analysis, was performed to ensure the GX Navigation Instrument System is acceptable for its intended use, to ensure functionality and compatibility with the Medtronic® StealthStation® System using the NavLock tracker, and to demonstrate substantial equivalence to the predicate instrument systems.

Substantial Equivalence:
GX Navigation Instrument System was shown to be substantially equivalent to the predicate devices Medtronic CD HORIZON® Spinal System (K170679), LifeSpine Nautilus/Avatar (K111953/K132760/K151196 & Life Spine ARX (K200070/K191575) in indications for use, design, function, materials used and mechanical performance.

Conclusion:
The information presented demonstrates the substantial equivalency of The GX Navigation Instrument System.