July 10, 2023

Spinal Simplicity LLC
Mr. Adam Rogers
Vice President of Regulatory and Engineering
6363 College Boulevard, Suite 320
Overland Park, Kansas 66211

Re: K221307
Trade/Device Name: Edge Upper Cervical System
Regulation Number: 21 CFR 888.3075
Regulation Name: Posterior cervical screw system
Regulatory Class: Class II
Product Code: NKG, KWP
Dated: June 5, 2023
Received: June 6, 2023

Dear Mr. Rogers:

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 -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

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.

510(k) Number *(if known)*
K221307

Device Name
Edge Upper Cervical System (UCS)

Indications for Use *(Describe)*

The Edge upper cervical system is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the cervical spine (C1 to C7) and the thoracic spine (T1 to T3):

- Traumatic spinal fractures and/or traumatic dislocations;
- instability or deformity;
- failed previous fusions (e.g., pseudarthrosis);
- tumors involving the cervical/thoracic spine;
- degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and
- degenerative disease of the facets with instability.

The Edge UCS is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion. The Edge UCS is intended for use only with the Innosys Anax™ OCT Spinal 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

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared:

Spinal Simplicity LLC
6363 College Blvd
Suite 320
Overland Park, KS 66211
Phone: (913) 451-4414
Facsimile: (913) 888-0075

Contact Person: Adam Rogers

Date Prepared: October 24, 2022

Name of Device:

Edge Upper Cervical System

Common / Classification Name:

Posterior Cervical Screw System, 21 CFR 888.3075, Class II / Appliance, Fixation, Spinal Interlaminal, 21 CFR 888.3050, Class II
Product codes: NKG/KWP

Predicate Devices:

neon3™ universal OCT by ulrich GmbH & Co. KG (K161032) – Primary Predicate
Depuy Synthes Symphony OCT System (K192646) – Reference Device
Medtronic Vertex Select (K123906) – Reference Device

Intended Use / Indications for Use:

The Edge upper cervical system is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the cervical spine (C1 to C7) and the thoracic spine (T1 to T3):

- Traumatic spinal fractures and/or traumatic dislocations;
- instability or deformity;
- failed previous fusions (e.g., pseudarthrosis);
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- degenerative disease of the facets with instability.

The Edge UCS is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion. The Edge UCS is intended for use only with the Innosys Anax OCT Spinal System.

Technological Characteristics:

The Edge UCS consists of a main body that clamps on to the posterior arch of C1 to provide fixation and stability. The Edge UCS is then connected to the Innosys Anax OCT instrumentation using polyaxial rods to form a posterior cervical construct, similar to that of the predicate devices. The Edge device is an additively manufactured clamp composed of two fixation jaws superior to the C1 posterior arch, an inferior jaw base, and two receiving joints for polyaxial rods. The Edge UCS accommodates varying patient anatomy by providing three implant sizes. The Edge UCS is additively manufactured from titanium alloy Ti6Al4V ELI and is designed with areas for bone graft to be placed on the medial and lateral bone contacting regions of the device.

Performance Data:

Test data and/or engineering analyses have been provided to describe the performance of the Edge UCS in the following test modalities:

- ASTM F1717 Static Axial Compression
- ASTM F1717 Static Torsion
- ASTM F1717 Dynamic Axial Compression
- ASTM F1717 Dynamic Torsion
- ASTM F1798 Static Axial Grip and Torsion Grip
- Custom Sawbones Pull Off Test

The data demonstrates that the subject Edge UCS device presents sufficient mechanical performance to support its intended use.

Bacterial endotoxin testing will be performed on all batches of sterile packed devices.

Substantial Equivalence:

The Spinal Simplicity Edge UCS is as safe and effective as the identified predicate device. The Edge device has the same intended use, indications for use, and similar technological characteristics and principles of operation as its predicate device. Differences between the subject and predicate devices are minor and do not raise any new issues of safety or effectiveness.