



April 28, 2020

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

Re: K200896
Trade/Device Name: Solstice CCI
Regulation Number: 21 CFR 888.3075
Regulation Name: Posterior Cervical Screw System
Regulatory Class: Class II
Product Code: NKG, KWP
Dated: March 19, 2020
Received: April 3, 2020

Dear Ms. 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,

Colin O'Neill, MBE
Acting 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

510(k) Number (if known)
K200896

Device Name
Solstice CCI

Indications for Use (Describe)

Solstice CCI is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, 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., pseudoarthrosis); tumors involving the cervical/thoracic spine; and 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 Solstice CCI 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.

In order to achieve additional levels of fixation, The Solstice CCI may be connected to the titanium Life Spine NAUTILUS Spine System using the 3.5mm/5.5mm titanium parallel connectors.

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
Solstice CCI**

Submitted By: Life Spine, Inc.
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510(k) Contact: Angela Batker
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Date Prepared: April 27th, 2020

Trade Name: Solstice CCI

Common Name: Spinal Interlaminar Fixation Orthosis

Classification: NKG CFR 888.3075, Class II
KWP 21 CFR 888.3050, Class II

Primary Predicate: Life Spine The Cranial Fusion System (K162266)

Additional Predicate: Life Spine Solstice OCT System (K142253)
Life Spine The Solstice OCT System (K170804)
Orthofix Centurion POCT System (K180025)

Device Description:

The Solstice CCI is a temporary, titanium alloy (6AL-4V-ELI per ASTM F 136), multiple component system comprised of a variety of non-sterile, single use implantable components. The system consists of an assortment of occipital plates, occipital bone screws, polyaxial screws, hooks, connectors, rods, and locking caps.

All implants are intended for single use only and should not be reused under any circumstances. **Do not use any of the Solstice CCI components with components from any other system or manufacturer. The components should never be reused under any circumstances.**

Indications for Use of the Device:

The Solstice CCI is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, 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., pseudoarthrosis); tumors involving the cervical/thoracic spine; and 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 Solstice CCI 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.

In order to achieve additional levels of fixation, The Solstice CCI may be connected to the titanium Life Spine NAUTILUS Spine System using the 3.5mm/5.5mm titanium parallel connectors.

Technological Characteristics:

The Solstice CCI is substantially equivalent to the predicate systems in terms of design, materials, indications for use and sizing.

Material:

This submission seeks clearance of a device made from titanium alloy (Ti-6Al-4V ELI) as described by ASTM F136. This is the same material used in the predicate devices Life Spine Solstice CCI (K162266).

Performance Data:

The Solstice CCI was tested according to ASTM F2706 which included Static & Dynamic Axial Compression Bending and Torsion.

Substantial Equivalence:

The Solstice CCI was shown to be substantially equivalent to the predicate devices in indications for use, design, function, materials used and mechanical performance.

Conclusion:

The information presented demonstrates the substantial equivalency of The Solstice CCI.