



Food and Drug Administration
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May 1, 2017

Life Spine, Inc.
Randy Lewis
General Manager
13951 S. Quality Drive
Huntley, Illinois 60142

Re: K162266
Trade/Device Name: The Cranial Fusion System
Regulatory Class: Unclassified
Product Code: NKG, KWP
Dated: March 29, 2017
Received: March 30, 2017

Dear Mr. Lewis:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K162266

Device Name

The Cranial Fusion System

Indications for Use (Describe)

The Cranial Fusion 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 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 Cranial Fusion System 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 Cranial Fusion System 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
The Cranial Fusion System

Submitted By: Life Spine, Inc.
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510(k) Contact: Randy Lewis
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Telephone: 847-884-6117
Fax: 847-884-6118

Date Prepared: April 26, 2017

Trade Name: The Cranial Fusion System

Common Name: Cervical Pedicle Screw Fixation Orthosis

Classification: Unclassified

Product Codes: NKG, KWP

Primary Predicate: The Globus QUARTEX Occipito-Cervico-Thoracic Spinal System (K161591)

Additional Predicate: Solstice OCT System (K142253)
The Sentinel Spinal System (K090343)
The Solanas Avalon Posterior Fixation System (K111076)
The Gibralt Occipital Spine System (K160697)

Device Description:

The Cranial Fusion System 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.

Intended Use of the Device:

The Cranial Fusion 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 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.

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Technological Characteristics:

The Cranial Fusion System components are made from materials that conform to titanium per ASTM F136. The subject and predicate devices have minor differences and do not raise any new issues of safety and effectiveness. Design, materials, indications for use and sizing are substantially equivalent between subject and predicates.

Performance Data:

Static compression, dynamic compression, dynamic and static torsion testing according ASTM F2706 was presented to demonstrate the substantial equivalency of The Cranial Fusion System.

Substantial Equivalence:

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