K111132 DEC - 9 2011

# Genesys Spine
# Anterior Cervical Plate System

## Premarket Notification

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| **SUBMITTED BY** | Genesys Spine<br>1250 Capital of Texas Highway South<br>Building Three, Suite 600<br>Austin, TX 78746 |
| **ESTABLISHMENT REGISTRATION NUMBER** | 3008455034 |
| **OWNER/OPERATOR NUMBER** | 10033848 |
| **CONTACT PERSON** | **Primary:**<br>Brian J. Bergeron<br>VP of Engineering<br>Genesys Spine<br>Phone: (512) 381-7071<br>Fax: (800) 817-4938<br><br>**Alternate:**<br>William Sowers<br>VP of Quality & Regulatory<br>Genesys Spine<br>Phone: (512) 381-7070<br>Fax: (800) 817-4938 |
| **DATE PREPARED** | 9 September 2011 |
| **CLASSIFICATION NAME / REFERENCE / PRODUCT CODE** | Spinal Intervertebral Body Fixation Orthosis.<br>21 CFR § 888.3060, KWQ |
| **DEVICE CLASS** | Class II |
| **COMMON NAME** | Spinal Fixation System |
| **PROPRIETARY NAME** | Genesys Spine Anterior Cervical Plate System |
| **PREDICATE DEVICES** | The Genesys Spine Anterior Cervical Plate System was determined to be substantially equivalent to the Synthes Anterior CSLP System [Synthes Spine, K000536 / K945700], Venus Anterior Cervical Plate Systems [Verticor LTD, K103137], Spider Cervical Plating System [X-Spine Systems, K052292], Trestle Anterior Cervical Plating System [Alphatec, K102820], and SmartLox Anterior Cervical Plate [Captiva]. |

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**DEVICE DESCRIPTION**

The Genesys Spine Anterior Cervical Plate System is indicated for temporary stabilization of the cervical spine during the development of solid spinal fusion. The system consist of multiple sizes (lengths) of plates, and screws that are to be inserted into the anterior surface of adjacent cervical vertebrae. The proposed device is applied after discectomy and insertion of either an autograft or allograft material in the interbody space, and acts to stabilize the spine during fusion. The plates are offered in 1, 2, 3, and 4 level constructs in various lengths to accommodate a variety of patient anatomies. Each plate has a pre-bent sagittal and lordotic curve as well as posterior ridges to aid in the placement. Fixation is achieved by inserting bone screws through the openings in the plate into the vertebral bodies of the cervical spine. The bone screws are offered in lengths of 10, 12, 14, and 16mm. The screws are offered in a Fixed or Variable angle option. The fixed screw has a larger 'neck' outer diameter that engages with the plate thereby limiting the conical rotation of the screw while the variable screw 'neck' outer diameter which allows for 24 degrees of motion during screw insertion. This feature will allow the surgeon more flexibility when inserting and seating the screws. The screws are offered in four (4) colors based on fixed or variable geometry or 3.75mm or 4.25mm OD. The plates include a nitinol securement tab, preassembled to the plate that covers the heads of the bone screws on the lateral sides to reduce the potential for screw back-out. Additionally, there is a ratcheting feature that provides an audible and tactile feel for the surgeon population during insertion.

**INDICATIONS:**

The Genesys Spine Anterior Cervical Plate system is intended for anterior screw fixation to the cervical spine. It is to be used in skeletally mature patients as an adjunct to fusion of the cervical spine (C2 to C7). The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusion in patients with degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), spondylolisthesis, trauma (i.e. fractures or dislocations), tumors, deformity (defined as kyphosis, lordosis, or scoliosis), pseudoarthrosis, failed previous fusion, and/or spinal stenosis.

**TEST DATA:**

Static compression bending, static torsion, and dynamic compression bending were performed on the worst case construct per ASTM F1717. Test results demonstrate that the Genesys Spine Anterior Cervical Plate System is substantially equivalent to the predicate device.

**PERFORMANCE DATA (NONCLINICAL AND/OR CLINICAL):**

NONCLINICAL PERFORMANCE AND CONCLUSION:

Finite element and material property analysis as well as design verification results demonstrate that the proposed device is substantially equivalent to the predicate device.

CLINICAL PERFORMANCE AND CONCLUSIONS:

Clinical data and conclusions were not needed for this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

DEC - 9 2011

Genesys Spine
% Mr. Brian J. Bergeron
Vice President of Engineering
1250 Capital of Texas Highway South
Building Three, Suite 600
Austin, Texas 78746

Re: K111132
Trade/Device Name: Genesys Spine Anterior Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: December 01, 2011
Received: December 02, 2011

Dear Mr. Bergeron:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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 yours,

For

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

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K111132

Device Name: **Genesys Spine Anterior Cervical Plate System**

Indications for Use:

The Genesys Spine Anterior Cervical Plate system is intended for anterior screw fixation to the cervical spine. It is to be used in skeletally mature patients as an adjunct to fusion of the cervical spine (C2 to C7). The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusion in patients with degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), spondylolisthesis, trauma (i.e. fractures or dislocations), tumors, deformity (defined as kyphosis, lordosis, or scoliosis), pseudoarthrosis, failed previous fusion, and/or spinal stenosis.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K111132

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