



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

Genesys Spine  
Mr. Dave Lamb  
Vice President of Compliance  
1250 Capital of Texas Highway South  
Building Three, Suite 600  
Austin, Texas 78746

September 3, 2015

Re: K150812

Trade/Device Name: Genesys Spine Apache™ Cervical Interbody Fusion System  
Regulation Number: 21 CFR 888.3080  
Regulation Name: Intervertebral body fusion device  
Regulatory Class: Class II  
Product Code: ODP  
Dated: July 28, 2015  
Received: July 30, 2015

Dear Mr. Lamb:

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 yours,

**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)

K150812

Device Name

Genesys Spine Apache™ Cervical Interbody Fusion System

Indications for Use (Describe)

When used as a cervical intervertebral body fusion device, the Genesys Spine Apache™ Interbody Fusion System is indicated for intervertebral body fusion in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level from the C2-C3 disc to the C7-T1 disc. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use with supplemental fixation (i.e. cleared cervical plating system) and with autograft to facilitate fusion. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

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.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services  
Food and Drug Administration  
Office of Chief Information Officer  
Paperwork Reduction Act (PRA) Staff  
[PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov)

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

## 510(K) SUMMARY

Submitter's Name:	Genesys Spine
Submitter's Address:	1250 Capital of Texas Highway South Building Three, Suite 600 Austin, Texas 78746
Submitter's Telephone:	512-381-7070
Submitter's Fax:	800-817-4938
Contact Name:	Dave Lamb
Date Summary was Prepared:	August 31, 2015
Trade or Proprietary Name:	Genesys Spine Apache™ Cervical Interbody Fusion System
Common or Usual Name:	Intervertebral Fusion Device, Cervical
Classification:	Class II per 21 CFR §888.3080
Product Codes:	ODP
Classification Panel:	Orthopedic and Rehabilitation Devices Panel
Primary Predicate	Genesys Spine Apache™ Interbody Fusion System (K103034)
Additional predicate	Eminent Spine Copperhead (K090064)

### DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Genesys Spine Apache™ Cervical Interbody Fusion System will be offered in various device configurations based on surgical approach and patient anatomy, and consist of a Genesys Spine cervical interbody fusion device, which may be implanted as a single device via an anterior approach.

### INDICATIONS FOR USE

When used as a cervical intervertebral body fusion device, the Genesys Spine Apache™ Interbody Fusion System is indicated for intervertebral body fusion in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level from the C2-C3 disc to the C7-T1 disc. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use with supplemental fixation (i.e cleared cervical plating system) and with autograft to facilitate fusion. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

## TECHNICAL CHARACTERISTICS

The Genesys Spine Apache™ Cervical Interbody Fusion System is comprised of various device configurations designed to accommodate patient anatomy and provide the surgeon with different surgical approach options.

The Genesys Spine Interbody Fusion System implant components are made of polyether ether ketone (Invibio PEEK Optima LT1) that conforms to ASTM F2026. Additionally, the devices contain tantalum markers (ASTM F560) to assist the surgeon with proper placement of the device. The additional implant offering being proposed has similar technological characteristics and identical indications as the currently cleared product line.

## PERFORMANCE DATA

Expulsion testing was conducted. Cross-Sectional Area calculations, FEA analysis, and projected area calculations show that a new worst-case device was not created. This Finite Element analysis tool was validated by the predicate system's mechanical test data and is sufficient to allow for a substantial equivalence designation for the subject device. In addition, the length, width, and height of the Cervical Interbody Fusion System implants fall within the scope of predicate devices already cleared.

## CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that Genesys Spine Apache™ Cervical Interbody Fusion System is substantially equivalent to the legally marketed predicate devices.