DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

July 28, 2016

Genesys Spine
Mr. Benjamin V. Keller
Product Development Engineer
1250 Capital of Texas Highway South
Building Three, Suite 600
Austin, Texas 78746

Re: K152099
Trade/Device Name: Genesys Spine Apache® Anchored Cervical Interbody Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion Device
Regulatory Class: Class II
Product Code: OVE
Dated: July 19, 2016
Received: July 21, 2016

Dear Mr. Keller:

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 Parts 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" (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 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,

Vincent J. Devlin -S

for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152099

Device Name
Genesys Spine Apache® Anchored Cervical Interbody Fusion System

Indications for Use *(Describe)*
The Genesys Spine Apache® Anchored Cervical Interbody Fusion System is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level from C2–T1. 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. These patients should have had six weeks of non-operative treatment.

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.

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"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:	512-381-7093
Submitter's Fax:	512-381-7076
Submitter's E-mail:	Ben.Keller@genesysspine.com
Contact Name:	Ben Keller
Date Summary was Prepared:	07/25/16
Trade or Proprietary Name:	Genesys Spine Apache® Anchored Cervical Interbody Fusion System
Common or Usual Name:	Intervertebral Fusion Device With Integrated Fixation, Cervical
Classification:	Class II per 21 CFR §888.3080
Product Codes:	OVE
Classification Panel:	Orthopedic and Rehabilitation Devices Panel
Predicate (unmodified) devices to Which Substantial Equivalence is Claimed:	LDR Spine Cervical Interbody Fusion System – ROI-C (K091088, K113559) [Primary Predicate], Exactech Acapella One Cervical Spacer System (K132582)

Question	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		X
Does the device contain components derived for a tissue or other biologic source?		X
Is the device provided sterile?		X
Is the device intended for single use?	X	
Is the device a reprocessed single use device?		X
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?		X
Does the submission include clinical information?		X
Is the device implanted?	X	

Genesys Spine regards information provided in support of this premarket notification to be confidential and proprietary and afforded such protection under 21CFR 807.95 and other applicable statutes. In accordance with the Safe Medical Devices Act of 1990, a 510(k) Summary of Safety and Effectiveness is included in this notification.

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Genesys Spine Apache® Anchored Cervical Interbody Fusion System includes a PEEK interbody that is implanted with two (2) titanium bone nails. The Apache® Anchored Cervical Interbody Fusion System was designed to provide additional biomechanical strength to traditional ACDF procedures through integrated fixation combined with supplemental fixation.

INDICATIONS FOR USE:

The Genesys Spine Apache® Anchored Cervical Interbody Fusion System is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level from C2–T1. 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. These patients should have had six weeks of non-operative treatment.

TECHNICAL CHARACTERISTICS:

The Genesys Spine Apache® Anchored Cervical Interbody Fusion System implants are comprised of two components; 1) PEEK interbodies with tantalum markers and 2) titanium alloy cervical bone nails. Both the interbodies and the cervical bone nails are offered in various sizes. The bone nails are inserted through the channels in the PEEK interbody and into the adjacent cervical vertebrae. The device is inserted after a discectomy and the integrated fixation provides additional stabilization to the spine during fusion.

The interbody devices are made of polyether-ether-ketone (Invibio's PEEK Optima LT1) that conforms to ASTM F2026. Additionally, the PEEK implants contain tantalum markers per ASTM F560 to assist the surgeon with proper placement of the device in the disc space. The bone nail components are manufactured from medical grade Ti-6Al-4V ELI titanium alloy per ASTM F-136.

NON-CLINICAL PERFORMANCE DATA:

The predetermined pass-fail criterion was that the mechanical test results for the Genesys Spine Apache® Anchored Cervical Interbody Fusion System be equivalent to (or greater than) previously cleared interbody fusion systems. Prior to performing mechanical testing, all possible configurations of the Apache® Anchored Cervical Interbody Fusion System constructs were analyzed in order to determine the worst case to be used for testing.

The Genesys Spine Apache® Anchored Cervical Interbody Fusion System was tested in static and dynamic axial compression and torsion per ASTM F2077-11, static subsidence per ASTM F2267-04, and expulsion testing per ASTM draft standard F-04.25.02.02. The system was also tested to determine the force for bone nail back-out under worst-case conditions.

The Genesys Spine Apache® Anchored Cervical Interbody Fusion System was evaluated in a cadaveric validation study.

CONCLUSION OF NON-CLINICAL TESTS:

The overall technological characteristics and mechanical performance data lead to the conclusion that the Genesys Spine Apache® Anchored Cervical Interbody Fusion System is substantially equivalent to the LDR Spine Cervical Interbody Fusion System – ROI-C (K091088, K113559) and the Exactech Acapella One Cervical Spacer System (K132582).

Ben Keller
Genesys Spine
07/25/16