DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Genesys Spine
Mr. Brian J. Bergeron
VP of Research & Development
1250 South Capital of Texas Highway
Building 3, Suite 600
Austin, Texas 78746

July 13, 2017

Re: K171656
Trade/Device Name: Genesys Spine Apache Interbody Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: June 15, 2017
Received: June 16, 2017

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 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

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)*
K171656

Device Name
Genesys Spine Apache Interbody Fusion System

Indications for Use *(Describe)*
The Genesys Spine Apache® Interbody Fusion System is indicated for intervertebral body fusion of the lumbar spine, from L2 to SI, in skeletally mature patients who have had six months of non-operative treatment. The device is intended for use at either one level or two contiguous levels for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use with supplemental fixation and with autograft to facilitate fusion.

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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4. 510(K) SUMMARY

	Primary	Secondary
Submitter's Name:	Genesys Spine	Genesys Spine
Submitter's Address:	1250 Capital of Texas Highway South Building Three, Suite 600 Austin, Texas 78746	1250 Capital of Texas Highway South Building Three, Suite 600 Austin, Texas 78746
Submitter's Telephone:	512-381-7071	512-381-7080
Submitter's Fax:	800-817-4938	800-817-4938
Contact Name:	Brian J. Bergeron	William W. Sowers
Date Summary was Prepared:	June 1, 2017	
Trade or Proprietary Name:	Genesys Spine Apache Interbody Fusion System	
Common or Usual Name:	Intervertebral Fusion Device	
Classification:	Class II per 21 CFR §888.3080	
Product Codes:	MAX	
Classification Panel:	Orthopedic and Rehabilitation Devices Panel	
Legally Marketed (unmodified) devices to Which Substantial Equivalence is Claimed:	Primary Predicate: Genesys Spine Apache Interbody Fusion System (K161438) Additional Predicate(s): Genesys Spine Apache Interbody Fusion System (K103034 / K130913 / K153123) Amendia (Spine Select, LLC) Turbo Prime IBD System (K080058)	

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

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

- Bi-laterally via a posterior (PLIF) approach
- As a single device via a transforaminal (TLIF) approach or
- As a single device via an anterior/anterolateral (ALIF) approach or
- As a single device via a lateral (LLIF) approach.

INDICATIONS FOR USE

The Genesys Spine Apache Interbody Fusion System is indicated for intervertebral body fusion of the lumbar spine, from L2 to SI, in skeletally mature patients who have had six months of non-operative treatment. The device is intended for use at either one level or two contiguous levels for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use with supplemental fixation and with autograft to facilitate fusion.

TECHNICAL CHARACTERISTICS

The Genesys Spine Apache 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 Apache Interbody Fusion System implants are manufactured from implantable, medical grade Ti-6Al-4V ELI titanium alloy per ASTM F136. The additional implant offering being proposed has similar technological characteristics and identical indications as the currently cleared product line.

PERFORMANCE DATA

Not Required. 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.

CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that Genesys Spine Apache® Interbody Fusion System is substantially equivalent to the Genesys Spine Interbody Fusion System (K161438), Genesys Spine Interbody Fusion System (K103034 / K130913 / K153123), and Amendia Turbo Prime IBD System (K080058).