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. Dave Lamb
Vice President of Compliance
1250 Capitol of Texas Highway South
Building Three, Suite 600
Austin, Texas 78746

July 21, 2016

Re: K161404
Trade/Device Name: Genesys Spine Apache® Lateral Lumbar Interbody Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: June 28, 2016
Received: June 30, 2016

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 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,

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)*
K161404

Device Name
GENESYS SPINE APACHE® LATERAL LUMBAR INTERBODY FUSION SYSTEM

Indications for Use *(Describe)*
The Genesys Spine Apache™ Lateral Lumbar Interbody Fusion System is indicated for intervertebral body fusion of the lumbar spine, from L2 to S1, 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 1 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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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:	800-817-4938
Contact Name:	Ben Keller
Date Summary was Prepared:	May 19th, 2016
Trade or Proprietary Name:	Genesys Spine Apache® Lateral Lumbar 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
Primary Predicate Device:	Genesys Spine Apache® Lateral Lumbar Interbody Fusion System (K130913)
Additional Predicate Devices:	- Genesys Spine Interbody Fusion System (K103034) - Medtronic Capstone Control Spinal System (K120368) - Cogent Spine Lateral Interbody System (K151406)

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The intent of this Special 510(k) is to add new components to the currently cleared Genesys Spine Apache® Lateral Lumbar Interbody Fusion System (K130913). This submission will offer various device configurations based on surgical approach and patient anatomy, and consist of a Genesys Spine Lumbar Interbody Fusion Device, which may be implanted as a single device via a lateral approach.

INDICATIONS FOR USE

The Genesys Spine Apache® Lateral Lumbar Interbody Fusion System is indicated for intervertebral body fusion of the lumbar spine, from L2 to S1, 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 1 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® Lateral Lumbar 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® Lateral Lumbar Interbody Fusion System implant components are made of polyetheretherketone (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

Cross-sectional area analysis, Finite Element Analysis (FEA), and projected area calculations demonstrated substantial equivalence to the predicate devices. The cross-sectional area analysis was used to determine the potential worst-case implant. A validated compressive FEA model was then used to determine the von Mises stresses. The maximum von Mises stress values were substantially lower in the subject device than the predicate device. Projected area calculations were used to determine if a new worst case was created for expulsion or subsidence. All of the performance data suggested that a new worst case was not created and that the subject device is substantially equivalent in the evaluated areas.

CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that Genesys Spine Apache® Lateral Lumbar Interbody Fusion System is substantially equivalent to the Genesys Spine Apache® Lateral Lumbar Interbody Fusion System, Genesys Spine Interbody Fusion System, Medtronic Capstone Control Spinal System, and Cogent Spine Lateral Interbody System.