December 12, 2019

Genesys Spine
Mr. William W. Sowers
VP of Engineering
1250 South Capital of Texas Highway, Building 3 Suite 600
Austin, Texas 78746

Re: K182987
Trade/Device Name: Genesys Spine 3DP Lumbar Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: December 6, 2019
Received: December 9, 2019

Dear Mr. Sowers:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Brent Showalter, PhD
Assistant Director (Acting)
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K182987

Device Name
Genesys Spine 3DP Lumbar Interbody System

Indications for Use *(Describe)*

The Genesys Spine 3DP Lumbar Interbody 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 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 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
Contact Name:	William W. Sowers
Submitter's Telephone:	512-381-7080
Submitter's Fax:	512-381-7076
Date Summary was Prepared:	October 26, 2018
Trade or Proprietary Name:	Genesys Spine 3DP Lumbar Interbody System
Common or Usual Name:	Intervertebral Fusion Device with Bone Graft, Lumbar
Classification Name:	Intervertebral Body Fusion Device
Classification:	Class II
Regulation Number:	21 CFR §888.3080
Product Codes:	MAX
Classification Panel:	Orthopedic Devices Panel
Legally Marketed (unmodified) devices to Which Substantial Equivalence is Claimed:	Primary Predicate: Apache Interbody Fusion System (Genesys Spine - K103034) Additional Predicates: Aries® Lumbar Interbodies (Osseus Fusion Systems, LLC – K181347) EIT Cellular Titanium® Cervical & Lumbar Cages (Emerging Implant Technologies – K170503), Apache Lateral Lumbar System (Genesys Spine – K161404), Apache Hyperlordotic ALIF System (Genesys Spine – K161438), and the Apache Lumbar PEEK Interbodies (Genesys Spine - K153123)

DEVICE DESCRIPTION:

The Genesys Spine 3DP Lumbar Interbody System is comprised of additively manufactured lumbar intervertebral body fusion devices. They are designed to provide mechanical support to the lumbar spine while arthrodesis occurs. Numerous styles, footprints, and sizes of interbodies are offered

including PLIFs, TLIFs, ALIFs, and LLIFs. The 3DP Lumbar Interbody System implants are manufactured from titanium Ti-6AL-4V ELI alloy.

INDICATIONS FOR USE

The Genesys Spine 3DP Lumbar Interbody 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 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 system is designed for use with supplemental fixation and with autograft to facilitate fusion.

TECHNOLOGICAL COMPARISON TO PREDICATES

The Genesys Spine 3DP Lumbar Interbody System was compared to the predicate systems and the designs, materials, features, functions, and intended uses were found to be substantially the same.

NON-CLINICAL PERFORMANCE EVALUATION

Performance evaluations were conducted on constructs representing the worst-case components (including static compression, static torsion, static compression shear, dynamic compression, dynamic torsion, dynamic compression shear [in accordance with ASTM F2077], subsidence [in accordance with ASTM F2267] and expulsion). The Genesys Spine 3DP Lumbar Interbody System was found to be substantially the same as predicate devices.

CONCLUSION

There are no significant differences between the Genesys Spine 3DP Lumbar Interbody System and other systems currently being marketed which would adversely affect the use of the product. It is substantially equivalent in design, material, features, function, and intended use.