August 29, 2019

Genesys Spine
Mr. Andrew C. Davison
VP of Quality & Regulatory Affairs
1250 Capital of Texas Highway South
Building 3, Suite 600
Austin, Texas 78746

Re: K192076
Trade/Device Name: Binary® Anterior Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: July 22, 2019
Received: August 2, 2019

Dear Mr. Davison:

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,

for RPJ

Ronald Jean, Ph.D.
Assistant Director
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)*
K192076

Device Name
Binary® Anterior Cervical Plate System

Indications for Use *(Describe)*
The Genesys Spine Binary Anterior Cervical Plate System is intended for anterior screw fixation to the cervical spine. It is to be used in skeletally mature patients as an adjunct to fusion of the cervical spine (C2 to C7). The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusion in patients with degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), spondylolisthesis, trauma (i.e. fractures or dislocations), tumors, deformity (defined as kyphosis, lordosis, or scoliosis), pseudoarthrosis, failed previous fusion, and/or spinal stenosis.

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

Submitter's Name:	Genesys Spine	
Submitter's Address:	1250 Capital of Texas Highway South Building Three, Suite 600 Austin, Texas 78746	
Contact Name:	Andrew C. Davison (Primary)	Benjamin V. Keller (Secondary)
Submitter's Telephone:	512-381-7070	512-381-7093
Submitter's Fax:	512-381-7076	512-381-7076
Date Summary was Prepared:	August 19, 2019	
Trade or Proprietary Name:	Binary® Anterior Cervical Plate System	
Common or Usual Name:	Spinal Intervertebral Body Fixation Orthosis	
Classification:	Class II	
Regulation Number:	21 CFR 888.3060 – Spinal Intervertebral Body Fixation Orthosis	
Product Codes:	KWQ	
Classification Panel:	Orthopedic and Rehabilitation Devices Panel	
Legally Marketed devices to Which Substantial Equivalence is Claimed:	Primary Predicate: Anterior Cervical Plate II System (Genesys Spine - K133245)	

PURPOSE OF THE 510(K)

The intent of this Special 510(k) is to:

1. Register additional Screws sizes to the components of the Binary® Anterior Cervical Plate System.
2. Register additional Cervical Plate sizes to the components of the Binary® Anterior Cervical Plate System.

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Genesys Spine Binary® Anterior Cervical Plate System components are temporary implants used to stabilize the cervical spine during the development of a solid spinal fusion in patients with degenerative disease, trauma (including fractures), and tumor pathology.

The Genesys Spine Binary® Anterior Cervical Plate System consists of multi-segmented titanium/nitinol bone plates of various sizes and lengths, titanium bone screws in various diameters and lengths, and associated instrumentation. Fixation is provided by the insertion of

bone screws into the anterior surface of adjacent cervical vertebrae. Fixation of the screws to the plate is accomplished by seating into the screw securement mechanism.

TECHNICAL CHARACTERISTICS

The Genesys Spine Binary® Anterior Cervical Plate System is comprised of multiple sizes of plates and screws that are inserted into the anterior surface of adjacent cervical vertebrae. The device is applied after discectomy and insertion of autograft or allograft in the interbody space, and acts to stabilize the spine during fusion.

INDICATIONS FOR USE

The Genesys Spine Binary Anterior Cervical Plate System is intended for anterior screw fixation to the cervical spine. It is to be used in skeletally mature patients as an adjunct to fusion of the cervical spine (C2 to C7). The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusion in patients with degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), spondylolisthesis, trauma (i.e. fractures or dislocations), tumors, deformity (defined as kyphosis, lordosis, or scoliosis), pseudoarthrosis, failed previous fusion, and/or spinal stenosis.

CONCLUSION

The overall technological characteristics have led to the conclusion that the additional implantable devices in the subject submission do not create a new worst case. As a result, the modified Genesys Spine Binary® Anterior Cervical Plate System is considered substantially equivalent to the previously cleared Genesys Spine Anterior Cervical Plate II System (Genesys Spine – K133245).