July 25, 2018

Republic Spine, L.L.C.
Mr. James Doulgeris
Director of Business Development and Quality Systems
350 Camino Gardens Boulevard, Suite 103
Boca Raton, Florida 33432

Re: K181495
Trade/Device Name: Republic Spine Dark Star Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB
Dated: June 1, 2018
Received: June 6, 2018

Dear Mr. Doulgeris:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ronald P. Jean -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)*

K181495

Device Name
Republic Spine Dark Star Spinal System

Indications for Use *(Describe)*

The Republic Spine Dark Star Spinal System is intended for posterior, non-cervical pedicle rigid fixation of the spine to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine (T1-S1):

- Degenerative Disc Disease (DDD);
- Spondylolisthesis;
- Trauma (i.e. fracture or dislocation);
- Spinal stenosis;
- Curvatures (i.e. scoliosis, kyphosis, and/or lordosis);
- Tumor;
- Pseudoarthrosis; and
- Failed previous 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) SUMMARY

Submitter's Name:	Republic Spine, LLC
Submitter's Address:	350 Camino Gardens Suite 103 Boca Raton FL 33432
Submitter's Telephone:	561-362-8094
Contact Person:	James Doulgeris james@rspine.com
Date Summary was Prepared:	24 July 2018
Trade or Proprietary Name:	Republic Spine Dark Star Spinal System
Common or Usual Name:	Thoracolumbosacral Pedicle Screw System
Classification:	Class II
Classification Name:	Thoracolumbosacral Pedicle Screw System
Regulation:	21 CFR 888.3070
Product Code:	NKB
Classification Panel:	Division of Orthopedic Devices

DEVICE DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:
The Republic Spine Dark Star Spinal System is a multi-component posterior spinal fixation system which consists of pedicle screws, rods, locking spacers, and cross-linking mechanism. The system is contains non-sterile single use titanium alloy (Ti-6Al-4V ELI) implantable components that comply with ASTM F136. Various sizes of these implants are available. Instrumentation is available for the delivery and removal of the Republic Spine Dark Star Spinal System. The system allows the surgeon to build a spinal implant construct to stabilize and promote spinal fusion.

INDICATIONS FOR USE

The Republic Spine Dark Star Spinal System is intended for posterior, non-cervical pedicle rigid fixation of the spine to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine (T1-S1):

- Degenerative Disc Disease (DDD);
- Spondylolisthesis;
- Trauma (i.e. fracture or dislocation);
- Spinal stenosis;
- Curvatures (i.e. scoliosis, kyphosis, and/or lordosis);
- Tumor;
- Pseudoarthrosis; and
- Failed previous fusion

PREDICATE DEVICE

Primary Predicate Device

510k Number	**Trade or Proprietary or Model Name**	**Manufacturer**
K150283	Dark Star Spinal System	Republic Spine

NON-CLINICAL PERFORMANCE DATA

The predicate Republic Spine Dark Star Spinal System has been previously tested in the following test modes:

- Static compression bending per ASTM F1717
- Static torsion per ASTM F1717
- Dynamic compression bending per ASTM F1717
- Torsional, Axial and Flexural Grip ASTM F1798-97

The subject modifications do not introduce a new, worst-case compared to the predicate devices tested per the standards identified above. Therefore, additional performance testing was not conducted for the modified devices.

CLINICAL PERFORMANCE DATA

Clinical performance data is not required to demonstrate substantial equivalence to the predicate.

SUMMARY

Documentation was provided to demonstrate that the Republic Spine Dark Star Spinal System is substantially equivalent to the legally marketed predicate. The devices and accessories included in the Subject device and the predicate devices are both pedicle screw systems as defined in 21 CFR 888.3070. The Republic Spine Dark Star Spinal System is substantially equivalent to the predicate devices in intended use, site of application, patient population, conditions of use, mechanical performances, basic design, and operating principles. The Republic Spine Dark Star Spinal System is comparable to its predicate in size and materials. Previous testing in accordance with ASTM 1717-14, and ASTM F1798-97 shows the mechanical strength of the subject device to be equivalent or better than the predicate devices.

SUBSTANTIAL EQUIVALENCE CONCLUSION

Basis of substantial equivalence of the modified device and predicate device is established on the following:

The Republic Spine Dark Star Spinal System and the predicate device system have the following similarities:

- Both systems have the same Indications for Use**.** The intended patient population and indications for use of the predicate system are unchanged.

- Both systems operate using the same fundamental scientific technology.
- Both systems incorporate the same basic implant designs.
- Both systems are manufactured from the same material.
- Both systems are provided non-sterile.
- Both systems use the same operational principles for the surgical implantation of the subject Screws.

The Republic Spine Dark Star Spinal System and the predicate device have the following differences:

- Additional screw sizes (lengths) added for solid, solid low top, cannulated low top, solid tower pedicle screws, cannulated tower and cannulated reduction pedicle screws.

Evaluation of the risks and performance data based on the differences between the subject device and predicate does not raise any new issues or concerns related to safety or effectiveness. It is concluded that the modified device, the Republic Spine Dark Star Spinal System is as safe and effective as the predicate device for its intended use, and is substantially equivalent to the legally marketed predicate device, the Republic Spine Dark Start Spinal System (K150283).