March 5, 2021

Republic Spine, LLC
James Doulgeris
Director of Product Development and Quality Systems
2424 N Federal Hwy, STE 257
Boca Raton, Florida 33431

Re: K201420
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, KWP
Dated: January 26, 2021
Received: January 27, 2021

Dear James 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/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,

Colin O'Neill, M.B.E.
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)*
K201420

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 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:
• Degenerative Disc Disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies);
• Spondylolisthesis;
• Trauma (i.e. fracture or dislocation);
• Spinal stenosis;
• Curvature (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.

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510(k) Summary

Sponsor	**Republic Spine, LLC** 2424 North Federal Hwy Suite 257 Boca Raton, FL, 33431
Establishment Number	3011796723
Point of Contact	James Doulgeris 2424 North Federal Hwy Suite 257 Boca Raton, FL, 33431 561-362-8094
Date	27 January, 2021
Trade Name	Republic Spine Dark Star Spinal System
Common Name	Spinal Pedicle Fixation Device
Classification Panel	Orthopedic
Classification	Class II
Regulation No.	21 CFR 888.3070, 21 CFR 888.3050
Regulation Name	Thoracolumbosacral pedicle screw system, Spinal interlaminal fixation orthosis
Product Code	NKB, KWP
Primary Predicate Device	K181495, Republic Spine Dark Star Spinal System
Additional Predicate Devices	K193100, OrthoPediatrics, Corp. K180179, K141186, Orthofix Inc K171421, VERTICALE® Posterior Spinal Fixation System
Device Description	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 contains non-sterile single use titanium alloy (Ti-6Al-4V ELI per ASTM F136) and Cobalt Chromium (CoCr per ASTM F1537). 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. The scope of the Republic Spine Dark Start Spinal System is being extended via a line extension to include additional rods, connectors, hooks and screws. New instrumentation will also be introduced to aid in the implantation of the new implants. The safety and effectiveness of the fenestrated screw have not been established when used in conjunction with bone cement or for use in patients

	with poor bone quality (e.g., osteoporosis, osteopenia). The fenestrated screws are intended to be used with saline or radiopaque dye.
Intended Use/ Indications for Use	The Republic Spine Dark Star Spinal System is intended for posterior, non-cervical pedicle 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: • Degenerative Disc Disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); • Spondylolisthesis; • Trauma (i.e. fracture or dislocation); • Spinal stenosis; • Curvature (i.e. scoliosis, kyphosis, and/or lordosis); • Tumor; • Pseudoarthrosis; and • Failed previous fusion.
Nonclinical Performance Data	The subject Republic Dark Star Spinal System implants were subjected to the following verification testing per required standards to establish substantial equivalent performance to the predicate device. • ASTM F1717: Static Axial Compression Bending • ASTM F1717: Dynamic Axial Compression Bending • ASTM F1717: Static Torsion • ASTM F1798: Static Axial Grip, Torsional Grip
Clinical Performance Data	Clinical performance data is not required to demonstrate substantial equivalence to the predicate device.
Substantial Equivalence Conclusion	Substantial equivalence of the subject device and predicate device(s) is based on the following: • The modified and predicate device(s) have the same intended use. • The modified and predicate devices(s) operate using the same fundamental scientific technology. • The modified and predicate devices(s) share the same functional and technological characteristics via the same operational principles. Evaluation of the risks and performance data of the subject device demonstrates it is substantially equivalent to predicate devices.