May 26, 2023

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

Re: K223096
Trade/Device Name: Dark Star Deformity Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB, KWP
Dated: May 18, 2023
Received: May 19, 2023

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 -S

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223096

Device Name
Dark Star Deformity Pedicle Screw System

Indications for Use *(Describe)*

The Republic Spine Dark Deformity Pedicle Screw 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
- Failed previous fusion

When used for posterior, non-cervical, pedicle screw fixation in pediatric patients, the Dark Star Deformity Pedicle Screw System implants are indicated as an adjunct to fusion to treat progressive spinal deformities (i.e., scoliosis, kyphosis, or lordosis) including idiopathic scoliosis, neuromuscular scoliosis, and congenital scoliosis. Additionally, the Dark Star Deformity Pedicle Screw System is intended to treat pediatric patients diagnosed with: spondylolisthesis/spondylolysis, fracture caused by tumor and/or trauma, pseudarthrosis, and/or failed previous fusion. This system is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

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

510(K) SUMMARY

Submitter's Name:	Republic Spine, LLC
Submitter's Address:	2424 North Federal Hwy, Suite 257 Boca Raton, FL 33431
Submitter's Telephone:	561-334-2421
Contact Person:	James Doulgeris 727-512-5461 James@rspine.com
Date Summary was Prepared:	May 18, 2023
Trade or Proprietary Name:	Dark Star Deformity Pedicle Screw System
Common or Usual Name:	Spinal Pedicle Fixation Device, Spinal Interlaminar Fixation Orthosis
Classification:	Class II per 21 CFR §888.3050 Class II per 21 CFR §888.3070
Product Code:	NKB, KWP
Classification Panel:	Spinal Devices (DHT6B)

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The Republic Spine Dark Star Deformity Pedicle Screw System (previously cleared as Dark Star Spinal System) is a multi-component posterior spinal fixation system which consists of pedicle screws, set screws, rods, hooks, connectors, and crosslinks. The system contains non-sterile single use components manufactured from 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 Deformity Pedicle Screw 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 Star Deformity Pedicle Screw System is being extended with this submission via a line extension to offer new implant options including connectors, pre-bent rods, crosslinks, and hooks and to offer implant design modifications to the uniplanar screws, to the connectors, and to the hooks. New instrumentation will also be introduced to aid in the implantation of the new and existing implants. The indications for use are being expanded to include pediatric applications.

INDICATIONS FOR USE

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TECHNOLOGICAL CHARACTERISTICS

The subject and predicate devices have identical technological characteristics and the minor differences do not raise any new issues of safety and effectiveness. Specially, the following characteristics are identical between the subject and predicates:

- Indications for Use
- Materials of manufacture
- Principles of Operation
- Fundamental scientific technologies
- Functional technological characteristics

Predicate Devices

510k Number	Trade or Proprietary or Model Name	Manufacturer	Product Code	Predicate Type
K201420	Dark Star Spinal System	Republic Spine, LLC	NKB, KWP	Primary
K142381	Xia® 3 Spinal System	Stryker Spine	NKB, KWP	Additional

PERFORMANCE DATA

The subject Dark Star Deformity Pedicle Screw System implants were subjected to the following abbreviated 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: Axial Grip
- ASTM F1798: TORSION GRIP

CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that the subject Dark Star Deformity Pedicle Screw System is substantially equivalent to the predicate device.