DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 29, 2015

Republic Spine, LLC
% Ms. Cheryl L. Wagoner
Wagoner Consulting, LLC
P.O. Box 15729
Wilmington, North Carolina 28408

Re: K150283
Trade/Device Name: Republic Spine Dark Star Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNH, MNI
Dated: April 9, 2015
Received: April 10, 2015

Dear Ms. Wagoner:

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. 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); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

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)*
K150283

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 (T1-S1):

- Severe Spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra
- Degenerative spondylolisthesis with objective evidence of neurologic impairment
- Trauma (i.e. fracture or dislocation)
- Spinal stenosis
- Curvature (i.e. scoliosis, kyphosis, and/or lordosis)
- Tumor
- Pseudoarthrosis (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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# 510(k) Summary
(as required by 21 CFR 807.92)

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| Date Prepared | April 24, 2015 |
| Submitter | Republic Spine LLC |
| Address | 3200 NE 14th Street Causeway<br>Suite 250<br>Pompano Beach, FL 33062 |
| Telephone | 954-249-0817 |
| Fax | 954-301-3343 |
| Contact Person | Rusty McCarver<br>Chief Operating Officer |
| email | rusty@rspine.com |

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| Trade Name | Republic Spine Dark Star Spinal System |
| Common Name | Spinal Pedicle Fixation Device |
| Panel Code | Orthopaedics/87 |
| Classification Name | Spondylolisthesis Spinal Fixation Device System (MNH)<br>Pedicle Screw Spinal System (MNI) |
| Class | Class II (Special Controls) |
| Regulation Number | 21 CFR 888.3070 |
| Product Code | MNH, MNI |

| **Predicate Device Name** | **510(k) Number** | **Manufacturer** |
|---|---|---|
| STARFIRE Pedicle Screw System | K102204 | Choice Spine |

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| **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 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. |

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| **Indications and Intended 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 (T1-S2):<br>• Severe Spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra<br>• Degenerative spondylolisthesis with objective evidence of neurologic impairment<br>• Trauma (i.e. fracture or dislocation)<br>• Spinal stenosis<br>• Curvature (i.e. scoliosis, kyphosis, and/or lordosis)<br>• Tumor<br>• Pseudoarthrosis (failed previous fusion) |

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| **Technological Characteristics and Substantial Equivalence** | 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 |

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| | 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. Testing in accordance with ASTM 1717-13, ASTM F543-07, and ASTM F1798-97 shows the mechanical strength of the subject device to be equivalent or better than the predicate devices. |

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| **Performance Data** | The potential hazards have been evaluated and controlled through a Risk Management Plan.<br><br>All testing met or exceeded the requirements as established by the test protocols and applicable standards. A review of the mechanical data indicates that the components of the Subject device are capable of withstanding expected loads without failure. The Subject device was therefore found to be substantially equivalent to the Predicates. Clinical data was not needed to support the safety and effectiveness of the Subject Device.<br>The following mechanical testing was performed:<br>• ASTM 1717 Static Compression Bending<br>• ASTM 1717 Dynamic Compression Bending<br>• ASTM 1717 Static Torsion<br>• ASTM F543-07: Static Torque to Failure<br>• ASTM F543-07: Axial Pullout<br>• ASTM F1798-97: Torsional, Axial and Flexural Grip |

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| **Conclusion** | Based on design, materials, intended use, technological characteristics, and comparison to predicate devices, the Subject Republic Spine Dark Star Spinal System has been shown to be substantially equivalent to legally marketed predicate device. |