



Republic Spine, LLC
James Doulgeris
Director of Business Development and Quality Systems
350 Camino Gardens Blvd Suite 103
Boca Raton, Florida 33432

September 12, 2019

Re: K190398

Trade/Device Name: Republic Spine Restore Intervertebral Body Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: July 17, 2019
Received: August 12, 2019

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/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 Melissa Hall
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

Indications for Use

510(k) Number (if known)

K190398

Device Name

Republic Spine Restore Intervertebral Body Fusion System

Indications for Use (Describe)

When used as a lumbar intervertebral body fusion device, the Republic Spine Restore Interbody Fusion System is indicated for intervertebral body fusion of the lumbar spine, from L2 to S1, in skeletally mature patients who have had six months of non-operative treatment. The device is intended for use at either one level or two contiguous levels for the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use with supplemental fixation and with autograft to facilitate 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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K190398: 510(K) Summary

Submitter's Name:	Republic Spine, LLC
Submitter's Address:	2424 N. Federal Hwy Suite 257 Boca Raton, FL 33431
Submitter's Telephone:	561-362-8094
Contact Person:	James Doulgeris james@rspine.com
Date Summary was Prepared:	17 July 2019
Trade or Proprietary Name:	Republic Spine Restore Intervertebral Body Fusion System
Common or Usual Name:	Intervertebral Body Fusion System
Classification:	Class II per 21 CFR 888.3080
Product Code:	MAX
Classification Panel:	Division of Orthopedic Devices

Description of the Device Subject to Premarket Notification

The Republic Spine Restore Intervertebral Body Fixation System will be offered in various device configurations based on surgical approach and patient anatomy, and consist of a Republic Spine lumbar intervertebral body fusion device, which may be implanted as a single device via an anterior, posterior, transforaminal or lateral approach.

Indications for Use

When used as a lumbar intervertebral body fusion device, Republic Spine Restore Intervertebral Body Fusion Spinal System is indicated for intervertebral body fusion of the lumbar spine, from L2 to S1, in skeletally mature patients who have had six months of non-operative treatment. The device is intended for use at either one level or two contiguous levels for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use with supplemental fixation and with autograft to facilitate fusion.

Technological Characteristics

The Republic Spine Restore Intervertebral Body Fusion System is comprised of various device configurations designed to accommodate patient anatomy and provide the surgeon with different surgical approach options.

The Republic Spine Restore Intervertebral Body Fusion System implant components are made of titanium alloy (Ti-6Al-4V ELI) per ASTM F136 or polyether ether ketone (Evonik Vestakeep® i4R) that conforms to ASTM F2026 with tantalum markers (ASTM F560) to assist the surgeon with the proper placement of the device. The subject devices have similar technological characteristics and identical indications as the currently cleared predicate devices.

Table 5-1 Predicate Devices

510k Number	Trade or Proprietary or Model Name	Manufacturer	Predicate Type
K090064	Intervertebral Body Fusion Spinal System	Eminent Spine	Primary

K112664, K162206	Zavation IBF System	Zavation LLC	Reference
K190889	Republic Spine Restore Cervical Interbody Fusion System	Republic Spine, LLC	Reference

Substantial Equivalence Conclusion

The basis of substantial equivalence of the subject device(s) and predicate device(s) is established on the following:

The subject device and the predicate devices have the following similarities:

- Both systems have the same indications for use. The intended patient population and intended use are the same.
- Both systems operate using the same fundamental scientific technology.
- Both systems incorporate the same basic implant design.
- Both systems use the same methods of sterilization.
- Both systems use the same operational principles for the surgical implantation of the interbody cages.
- Both systems are manufactured from the same materials.

The subject device and the predicate devices have the following differences:

- Minor dimensional differences in height, width and depth.

Performance Data

The subject PEEK device is considered worst case and therefore, was utilized during design verification mechanical bench tests to address the design differences between the subject device(s) and the predicate device(s). An engineering analysis consisting of FEA was conducted to determine the worst-case size for testing. The worst case size for the subject device has been tested in the following test modes:

- Static axial compression per ASTM F2077
- Dynamic axial compression per ASTM F2077
- Static subsidence per ASTM F2267
- Static expulsion

Conclusions: The results of the testing demonstrate that both the subject PEEK and Ti devices are substantially equivalent to the predicate.

Conclusion

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