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

June 19, 2019

Re: K190889
Trade/Device Name: Republic Spine Restore Cervical Interbody Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP
Dated: March 29, 2019
Received: April 24, 2019

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,

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

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)*
K190889

Device Name
Republic Spine Restore Cervical Interbody Fusion System

Indications for Use *(Describe)*
When used as a cervical intervertebral body fusion device, the Republic Spine Restore Cervical Interbody Fusion System is indicated for intervertebral body fusion in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level from the C2-C3 disc to the C7-T1 disc. DDD is defined as discogenic pain 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. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

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

Date	June 18th, 2019
Sponsor	Republic Spine, LLC 2424 N. Federal Hwy Suite 257 Boca Raton, FL 33421
Phone	561-362-8094
Contact Person	James Doulgeris
Proposed Proprietary Trade Name	Republic Spine Restore Cervical Interbody Fusion System
Regulatory Class	Class II
Common Name:	Intervertebral fusion device with bone graft, cervical
Classification Name	21 CFR 888.3080 Spinal Intervertebral Body Fusion Device
Product Code	ODP
Purpose of Submission	The purpose of this submission is to gain clearance for the Republic Spine Restore Cervical Interbody Fusion System
Device Description	The Republic Spine Restore Cervical Interbody Fusion System will be offered in various device configurations based on surgical approach and patient anatomy, and consist of a Republic Spine Restore cervical interbody fusion device, which is intended to be implanted as a single device via an anterior approach.
Indications for Use	When used as a cervical intervertebral body fusion device, the Republic Spine Cervical Interbody Fusion System is indicated for intervertebral body fusion in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level from the C2-C3 disc to the C7-T1 disc. DDD is defined as discogenic pain 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. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.
Materials	The Republic Spine Restore Cervical Interbody Fusion System implant components are made of titanium alloy (Ti-6AL-4 ELI) per ASTM F136 or polyether ether ketone (Evonik Vestakeep®) that conforms to ASTM F2026. Additionally, the PEEK devices contain tantalum markers (per ASTM F560) to assist the surgeon with proper placement of the device. The additional implant offering being proposed has similar technological characteristics and identical indications as the currently cleared predicates

Primary Predicate Eminent Spine Copperhead (K090064)

Additional Predicate(s) Zavation IBF (K181246)
Choice Spine (K183397)

Reference Device(s) Republic Spine (K150283)

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

Mechanical Testing:

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). A reduced sample size of titanium cages was tested alongside the PEEK cages to verify that they performed equivalent to or greater than the PEEK interbody cages.

- ASTM F2267 – Static Subsidence
  - Purpose: to verify that the interbody cage will not subside when under average daily living forces for both materials.
- ASTM 2077 – Static/Dynamic Compression & Static/Dynamic Torsion
  - Purpose: to verify that the interbody cage would not fail when under average daily living forces for both materials.
- Expulsion Testing
  - Purpose: to verify that the interbody cage would not dislodge under average daily living forces for both materials.
- Conclusions
  - The results of the testing demonstrate that both the subject PEEK and Ti devices are substantially equivalent to the predicate.

Conclusions

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).