January 13, 2023

Bright Spine
℅ Bahram Parvinian
Founder & Principal Consultant
Lighthouse Regulatory Consulting Group
5801 Nicholson Lane, Apt. 1705
North Bethesda, Maryland 20852

Re: K221542
Trade/Device Name: Galileo Vertebral Body Replacement Device
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: PLR
Dated: December 14, 2022
Received: December 19, 2022

Dear Bahram Parvinian:

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,

Katherine D. Kavlock -S

for
Brent Showalter, Ph.D.
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.

Submission Number *(if known)*

K221542

Device Name

Galileo Vertebral Body Replacement Device

Indications for Use *(Describe)*

When used as a single-level partial vertebral body replacement device, the Galileo™ devices are indicated for use in the cervical spine (C2-T1) of skeletally mature patients for the partial replacement (i.e., partial vertebrectomy) of a vertebral body resected or excised for the treatment of tumors, or trauma/fracture, or osteomyelitis, or to achieve decompression of the spinal cord and neural tissues in cervical degenerative disorders. The device is intended for use with autograft or allogenic bone graft comprising cancellous and/or corticocancellous bone graft. When the Galileo™ device is used as a single-level, partial vertebral body replacement device, supplemental fixation may be used.

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.

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510(k) Summary: Galileo VBR

In accordance with 21 CFR 807.92 of the Federal Code of Regulations

Date Prepared	May 5, 2022
Submitted By	Bright Spine LLC Robert Simonson t 561-289-9378 r@brightspine.com
Primary Contact	Bahram Parvinian PhD, Founder and Principal Consultant Lighthouse Regulatory Consulting Group LLC (301)938-7669 Bahram@lighthouseregulatory.com
Trade Name	Galileo Vertebral Body Replacement Device
Common Name	Vertebral body replacement device
Classification Name	Spinal intervertebral body fixation orthosis
Class	II
Product Code	PLR
CFR Section	21 CFR section 888.3060
Device Panel	Orthopedic
Primary Predicate Device	Galileo Vertebral Body Replacement Device (K192145)
Device Description	The Galileo Vertebral Body Replacement device is a surgical grade titanium (Ti-6A1-4V) device and is available in various widths and heights. It has openings of various sizes to allow for the placement of bone graft and for the free flow of cells between the bone graft and the bone of the patient. It is intended for partial vertebral body replacement in a single vertebra and to hold bone graft material.
Materials	Titanium (Ti-6A1-4V)
Intended Use	Partial cervical vertebral body replacement

<table>
<tr><td>Substantial Equivalence Claimed to Predicate Device</td><td>Galileo VBR is substantially equivalent to the predicate device in terms of intended use, design, materials used, mechanical safety and performances.</td></tr>
<tr><td>Indications for Use</td><td>When used as a single-level vertebral body replacement device, the Galileo™ devices are indicated for use in the cervical spine (C2-T1) of skeletally mature patients for the partial replacement (i.e., partial vertebrectomy) of a vertebral body resected or excised for the treatment of tumors, or trauma/fracture, or osteomyelitis, or to achieve decompression of the spinal cord and neural tissues in cervical degenerative disorders. The device is intended for use with autograft or allogenic bone graft comprising cancellous and/or corticocancellous bone graft. When the Galileo™ device is used as a single-level, partial vertebral body replacement device, supplemental fixation may be used</td></tr>
<tr><td>Summary of the technological characteristics compared to predicate</td><td>Galileo VBR has the same intended use and Indications For Use as K192145. The Galileo VBR includes four additional sizes:
<table><tr><th>A (width)</th><th>B (height)</th><th>C (depth)</th></tr><tr><td>7 mm</td><td>7 mm</td><td>12 mm</td></tr><tr><td>8 mm</td><td>8 mm</td><td>12 mm</td></tr><tr><td>9 mm</td><td>9 mm</td><td>12 mm</td></tr><tr><td>10 mm</td><td>10 mm</td><td>12 mm</td></tr></table>
There were no changes made to the device design, materials, or manufacturing method.</td></tr>
<tr><td>Non-clinical Test Summary</td><td>Mechanical performance tests were conducted following the ASTM F2077 (Test methods for intervertebral body fusion devices). All tests were passed.</td></tr>
<tr><td>Clinical Test Summary</td><td>Not Applicable</td></tr>
<tr><td>SE conclusion</td><td>The intended use and technological characteristics of Galileo VBR is the same as the identified predicate. The Galileo VBR has additional sizes compared to the predicate; however, these new device sizes do not result in new questions of safety and effectiveness. Based on the required design verification and validation activities, Galileo VBR is substantially equivalent to the identified predicate.</td></tr>
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