October 9, 2019

Legend Spine Technologies
% Christine Scifert, M.S., M.E.M.
Exec. VP
MRC-X, LLC
6075 Poplar Ave
Memphis, Tennessee 38119

Re: K192208
Trade/Device Name: CORNICE Cervical Spacer System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP
Dated: August 8, 2019
Received: August 14, 2019

Dear Christine Scifert:

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 Ronald P. Jean, Ph.D.
Director (Acting)
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)*
K192208

Device Name
LEGEND Spine CORNICE Cervical Spacer System

Indications for Use *(Describe)*
The LEGEND Spine CORNICE Cervical Spacer System is indicated for use as an intervertebral body fusion device in skeletally mature patients with cervical disc degeneration and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at one or two contiguous levels from C2 to T1. These patients should have had six weeks of non-operative treatment. The LEGEND Spine CORNICE Cervical Spacer System is also to be used with supplemental fixation system that have been cleared for use in the cervical spine. The LEGEND Spine CORNICE Cervical Spacer System is designed for use with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

LEGEND Spine CORNICE Cervical Spacer System

October 4, 2019

Company: Legend Spine Technologies
1803 Apple Tree Lane
Bethlehem, PA 18015

Primary Contact: Christine Scifert
Phone: 901-831-8053

Company Contact: Steve Marinelli, PE
Phone: 267-566-3273
s.marinelli@legend-spine.com

Trade Name: LEGEND Spine CORNICE Cervical Spacer System

Common Name: Intervertebral Body Fusion Device

Classification: II

Regulation Number: 888.3080

Panel: 87-Orthopedic

Product Code(s): ODP

Device Description: The LEGEND Spine CORNICE Cervical Spacer System is an Anterior Cervical Interbody Fusion Device that has a hollow chamber to permit packing with bone graft to facilitate fusion. The superior and inferior surfaces of the device have a pattern of teeth to provide increased stability and to help prevent movement of the device. The Legend Spine CORNICE Spacers are made from either PEEK (VESTAKEEP i4 R per ASTM F2026) radiolucent material with embedded tantalum (ASTM F560) x-ray markers or Titanium Alloy conforming to ASTM F136.

Indications for Use: The LEGEND Spine CORNICE Cervical Spacer System is indicated for use as an intervertebral body fusion device in skeletally mature patients with cervical disc degeneration and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at one or two contiguous levels from C2 to T1. These patients should have had six weeks of non-operative treatment. The LEGEND Spine CORNICE Cervical Spacer System is also to be used with supplemental fixation system that have been cleared for use in the cervical spine. The LEGEND Spine CORNICE Cervical Spacer System is designed for use with autogenous

and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion.

Substantial Equivalence: The subject components were demonstrated to be substantially equivalent to the following systems previously cleared by the FDA:

Primary Predicate:
K181140: Axis Chena Cervical PEEK Spacer System

Secondary Predicates:
K111983: Zimmer Biomet Vista-S
K120275: Depuy Synthes ACIS
K160125: K2M Cascadia

Reference Device:
K180071: STYLO-T Interbody Cage

The subject components are similar in indications, geometry, and materials to the predicates.

Performance Testing: Static and dynamic axial compression, static and dynamic compression shear, expulsion, and subsidence testing were completed for the CORNICE Spacer according to ASTM F2077-14, ASTM F2267-04, and the Class II Special Controls Guidance Document: Intervertebral Body Fusion Device issued June 12, 2007. Performance testing demonstrates that the subject device meets or exceeds performance of predicate devices demonstrating that the subject devices are substantially equivalent to the predicate devices.

Conclusion

Based on the test results and the comparison to the predicate devices, the subject device is determined to be substantially equivalent to the predicate devices.