May 3, 2018

Legend Spine Technologies
Christine Scifert
Exec. VP
MRC/X, LLC
6075 Poplar Avenue
Memphis, Tennessee 38119

Re: K180071
Trade/Device Name: STYLO Interbody Fusion Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: April 2, 2018
Received: April 3, 2018

Dear Ms. 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. 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180071

Device Name
STYLO Interbody Fusion Device

Indications for Use *(Describe)*

The LEGEND Spine STYLO Interbody Fusion Device is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). LEGEND Spine STYLO Interbody Fusion Device is to be used with autologous bone graft and implanted via an open transforaminal or posterior approach.

LEGEND Spine STYLO Interbody Fusion Device implants are to be used with supplemental fixation. Patients should have at least six (6) months 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.

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

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510(k) Summary

STYLO Interbody Fusion Device

April 27, 2018

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

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

Company Contact: Gwendolyn DeBoer
Phone: 610-366-0077
contact@legendspine.net

Trade Name: STYLO Interbody Fusion Device

Common Name: Intervertebral Fusion Device with Bone Graft Lumbar

Classification: II

Classification Name: Intervertebral Body Fusion Device

Regulation Number: 888.3080

Panel: 87-Orthopedic

Product Code(s): MAX

Device Description: The Legend Spine Technologies STYLO Interbody Fusion Device is an Interbody Fusion Device that has a hollow chamber to permit packing with autologous 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 Technologies STYLO interbody implants are made from either PEEK radiolucent material with embedded tantalum x-ray markers (ASTM F2026 and ASTM F560) or titanium alloy conforming to ASTM F136.

Indications for Use: The LEGEND Spine STYLO Interbody Fusion Device is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). LEGEND Spine STYLO

Interbody Fusion Device is to be used with autologous bone graft and implanted via an open transforaminal or posterior approach.

LEGEND Spine STYLO Interbody Fusion Device implants are to be used with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

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

Primary Predicate:

- Medtronic CAPSTONE® CONTROL Spinal System (K171107)

Secondary Predicates:

- Medtronic CAPSTONE® PEEK Spinal System (K133650)
- Camber Spine Technologies, TLS 5.0 Interbody Cage (K121254)

The subject STYLO Interbody Fusion Device is made from PEEK/Tantalum and Titanium Alloy have demonstrated to be substantially equivalent to the previously cleared devices cleared under K171107, K133650, and K121254 as the products are similar in indications, materials and geometry.

Performance Testing: Static and dynamic axial compression, static and dynamic compression shear, expulsion, and subsidence testing were completed for the STYLO Interbody Fusion Device 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.