Captiva Spine, Inc.
Jackie Ferro
VP Quality Assurance & Regulatory Affairs
967 N. Alternate A1A, Suite 1
Jupiter, Florida 33477

August 13, 2018

Re: K180990
Trade/Device Name: TirboLOX-L™ Lumbar IBFD
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: July 11, 2018
Received: July 13, 2018

Dear Ms. Ferro:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

Brent Showalter -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)*

K180990

Device Name
TirboLOX-L™ Lumbar IBFD

Indications for Use *(Describe)*

The Captiva Spine TirboLOX-L™ Lumbar IBFD is indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. Patients should have received 6 months of non-operative treatment prior to treatment with the devices. The device must be used with supplemental fixation and must be used with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. The DDD patients may also have up to a Grade I spondylolisthesis or retrolisthesis at the involved level(s).

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: TirboLOX-L™ Lumbar IBFD	
Manufacturer / Submitter	Captiva Spine, Inc. 967 N. Alternate A1A Ste.1 Jupiter, FL 33477-3206
Contact Person	Jackie Ferro VP Quality Assurance & Regulatory Affairs Phone: (877) 772-5571 x719 Fax: (866) 318-3224 Email: jackie.ferro@captivaspine.com
Date Prepared	July 11, 2018
Trade Name	TirboLOX-L™ Lumbar IBFD
Common Name	Intervertebral Fusion Device with Bone Graft, Lumbar
Proposed Class	Class II
Classification Name	Intervertebral Body Fusion Device (21 CFR §888.3080)
Product Code	MAX
Classification Panel	Division of Orthopedic Devices
Predicate Devices	Primary Predicate: • K171351 Posterior Spine Truss System (PSTS) Interbody Fusion Device, 4WEB, Inc. Additional Predicates: • K122956 FuseLOX® Lumbar Interbody System, Captiva Spine, Inc. • K150481 Cascadia Interbody System, K2M • K172888 EIT Cellular Titanium PLIF Cages, EIT Emerging Implant Technologies GmbH • K170341 Medussa-PL Cage, Medyssey USA, Inc. • K153400 ProLift® Expandable System, Life Spine
Submission Scope	The purpose of this submission is to request market clearance for a new product offering of Captiva Spine, Inc. which is an intervertebral body fusion device product called TirboLOX-L™ Lumbar IBFD.
Device Description	The Captiva Spine, Inc. TirboLOX-L™ Lumbar IBFD is made from a titanium alloy (Ti-6Al-4V ELI per ASTM F3001 and TI-6Al-4V ELI per ASTM F136) and is created using 3D printing technologies. The implants are available in various footprints to accommodate a variety of patient anatomies and is provided sterile. The device has a window in the center of device to accept autogenous bone and/or allogenic bone graft. The implant is available in the following configurations: PLIF (Lordotic; 3°, 6°, and 15°, Convex) and TLIF (Straight, Curved Lordotic and Curved Parallel).

Indications for Use	The Captiva Spine, Inc. TirboLOX-L™ Lumbar IBFD is indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. Patients should have received 6 months of non-operative treatment prior to treatment with the devices. The device must be used with supplemental fixation and must be used with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. The DDD patients may also have up to a Grade I spondylolisthesis or retrolisthesis at the involved level(s).
Summary of the Technological Characteristics	The TirboLOX-L™ Lumbar IBFD and its predicate devices have nearly identical technological characteristics and the minor differences do not raise any new issues of safety and effectiveness. Specifically, the following characteristics are identical between the subject and predicates: • Indications for use • Materials of manufacture • Structural support mechanism
Performance Data	The TirboLOX-L™ Lumbar IBFD has been tested in the following test modes: • ASTM F2177-14 o Static Axial Compression o Static Shear o Dynamic Axial Compression o Dynamic Shear • ASTM 3267-04 o Static Subsidence • AAMI ST72 o Bacterial Endotoxin Testing Additionally, expulsion testing was performed. The results of this non-clinical testing show that the strength of the TirboLOX-L™ Lumbar IBFD is sufficient for its intended use and is substantially equivalent to legally marketed predicate devices.
Conclusion	The overall technology characteristics and mechanical performance data lead to the conclusion that the TirboLOX-L™ Lumbar IBFD is substantially equivalent to the predicate devices.