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

September 19, 2018

Re: K181229
Trade/Device Name: TirboLOX-C™ Cervical IBFD
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP
Dated: August 17, 2018
Received: August 21, 2018

Dear Jackie 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)*

K181229

Device Name
TirboLOX-C™ Cervical IBFD

Indications for Use *(Describe)*

The Captiva Spine TirboLOX-C™ Cervical IBFD is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine at one-disc level. DDD is defined as neck pain of discogenic origin with the degeneration of the disc confirmed by history and radiographic studies. The Captiva Spine TirboLOX-C™ Cervical IBFD is used to facilitate fusion in the cervical spine and is placed via an anterior approach at the C3 to C7 disc levels with autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone graft. Patients should have at least six weeks of non-operative treatment prior to treatment with an intervertebral body fusion device. The device must be used with supplemental fixation.

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: TirboLOX-C™ Cervical IBFD | |
|---|---|
| Manufacturer / Submitter | Captiva Spine, Inc.<br>967 N. Alternate A1A Ste.1<br>Jupiter, FL 33477-3206 |
| Contact Person | Jackie Ferro<br>VP Quality Assurance & Regulatory Affairs<br>Phone: (877) 772-5571 x719<br>Fax: (866) 318-3224<br>Email: jackie.ferro@captivaspine.com |
| Date Prepared | September 13, 2018 |
| Trade Name | TirboLOX-C™ Cervical IBFD |
| Common Name | Intervertebral Fusion Device with Bone Graft, Cervical |
| Proposed Class | Class II |
| Classification Name | Intervertebral Body Fusion Device (21 CFR §888.3080) |
| Product Code | ODP |
| Classification Panel | Division of Orthopedic Devices |
| Predicate Devices | Primary Predicate:<br>• K110585: FuseLOX Cervical IBF System, Captiva Spine, Inc.<br>Additional Predicates:<br>• K180990, TirboLOX-L™ Lumbar IBFD, Captiva Spine Inc.<br>• K150765, K1251103, K113559: ROI-C, LDR<br>• K153250: Renovis Tesera SC Standalone Anterior Cervical Fusion (ACF) System, Renovis Surgical Technologies, Incorporated<br>• K120275: Synthes ACIS, Synthes Spine<br>• K170550: Camber Spine Technologies Coveris Cervical Cage System, Camber 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 for the cervical spine called TirboLOX-C™ Cervical IBFD. |
| Device Description | The Captiva Spine, Inc. TirboLOX-C™ Cervical IBFD is made from a titanium alloy 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: lordotic, anatomically correct and parallel. |

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|---|---|
| Indications for Use | The Captiva Spine TirboLOX-C™ Cervical IBFD is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine at one-disc level. DDD is defined as neck pain of discogenic origin with the degeneration of the disc confirmed by history and radiographic studies. The Captiva Spine TirboLOX-C™ Cervical IBFD is used to facilitate fusion in the cervical spine and is placed via an anterior approach at the C3 to C7 disc levels with autograft bone and/or allogenic bone graft composed of cancellous and/or corticocancellous bone graft. Patients should have at least six weeks of non-operative treatment prior to treatment with an intervertebral body fusion device. The device must be used with supplemental fixation. |
| Summary of the Technological Characteristics | The TirboLOX-C™ Cervical 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:<br>• Indications for use<br>• Materials of manufacture<br>• Structural support mechanism |
| Performance Data | The TirboLOX-C™ Cervical IBFD has been tested in the following test modes:<br>• ASTM F2077-14<br>o Static Axial Compression<br>o Static Shear<br>o Static Torsion<br>o Dynamic Axial Compression<br>o Dynamic Shear<br>o Dynamic Torsion<br>• ASTM 2267-04<br>o Static Subsidence<br>• ASTM F1978-12<br>o Abrasion Resistance<br>• ASTM F1877-16<br>o Wear Debris<br>Additionally, expulsion testing was performed. The results of this non-clinical testing show that the strength of the TirboLOX-C™ Cervical 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-C™ Cervical IBFD is substantially equivalent to the predicate devices. |