January 31, 2020

Captiva Spine, Inc.
George Chaux
Systems & Regulatory Compliance Manager
967 N. Alternate A1A Suite 1
Jupiter, Florida 33477

Re: K193270
Trade/Device Name: CapLOX II®/TowerLOX® MIS Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB
Dated: January 13, 2020
Received: January 15, 2020

Dear George Chaux:

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)*
K193270

Device Name
CapLOX II® / TowerLOX® MIS Pedicle Screw System

Indications for Use *(Describe)*
The CapLOX II® / TowerLOX® MIS Pedicle Screw System is a posterior, non-cervical pedicle fixation system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine including degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, pseudarthrosis and failed previous fusion.

In addition, when used as a pedicle screw fixation system, the CapLOX II® / TowerLOX® MIS Pedicle Screw System is intended for skeletally mature patients with severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar-first sacral, L5-S1 vertebra, who are receiving fusion by autogenous bone graft only, who are having the device attached to the lumbar and sacral spine (levels may be from L3 to the sacrum/ilium), who are having the device removed after the attainment of a solid 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.

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510(k) Summary: CapLOX II® / TowerLOX® MIS Pedicle Screw System Line Extension	
Manufacturer / Submitter	Captiva Spine, Inc. 967 N. Alternate A1A Ste.1 Jupiter, FL 33477-3206
Contact Person	George Chaux Systems & Regulatory Compliance Manager Phone: (877) 772-5571 x719 Fax: (866) 318-3224 Email: george.chaux@captivaspine.com and regulatory@captivaspine.com
Date Prepared	November 22, 2019
Trade Name	CapLOX II® / TowerLOX® MIS Pedicle Screw System
Common Name	Pedicle Screw System
Proposed Class	Class II
Classification Name	Thoracolumbosacral pedicle screw system (21 CFR § 888.3070)
Product Code	NKB
Classification Panel	Division of Orthopedic Devices
Predicate Devices	Primary Predicate: • CapLOX II® / TowerLOX® Pedicle Screw System (K131538)
Submission Scope	The purpose of this submission is the addition of a line extension of a 4.5mm pedicle screw and instrumentation in order to provide additional device offerings under the CapLOX II® / TowerLOX® MIS Pedicle Screw System portfolio when performing surgical corrections to the thoracic, lumbar and sacral spine using minimally invasive surgical techniques.
Device Description	The CapLOX II® / TowerLOX® MIS Pedicle 4.5mm Screw System is an implant device made from a titanium alloy Ti-6Al-4V ELI per ASTM F136. It is to be implanted from the posterior approach. The screws are currently available in diameters from 4.9-9.0mm and in lengths frOm 30-100mm. The line extension will include the addition of 4.5mm screws for the CapLOX II® /TowerLOX® MIS Pedicle Screw System in lengths of 30-55mm. Additional instrumentation will also be added to the system. Overall, the system includes pedicle screws, and the instrumentation in order to complete the procedure and implant construct when performed using minimally invasive surgical techniques.

Indications for Use	The CapLOX II® / TowerLOX® MIS Pedicle Screw System is a posterior, non-cervical pedicle fixation system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine including degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, pseudarthrosis and failed previous fusion. In addition, when used as a pedicle screw fixation system, the CapLOX II® / TowerLOX® MIS Pedicle Screw System is intended for skeletally mature patients with severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar-first sacral, L5-S1 vertebra, who are receiving fusion by autogenous bone graft only, who are having the device attached to the lumbar and sacral spine (levels may be from L3 to the sacrum/ilium), who are having the device removed after the attainment of a solid fusion.
Summary of the Technological Characteristics	All CapLOX II® / TowerLOX® MIS Pedicle Screws are made from titanium alloy that conforms to ASTM F136. The addition of 4.5mm and instrumentation have been assessed using risk management techniques and were concluded as not creating a new worst case when compared against the predicate devices. The subject and predicate devices have the following characteristics that are identical: • Indications for Use • Materials of manufacture • Structural support mechanism The minor differences in the subject and predicate devices were assessed and concluded as not raising any new issues for safety and effectiveness.
Performance Data	Engineering Analysis and Dynamic Compression Bending testing per ASTM F1717 were conducted to confirm that introduction of the 4.5mm pedicle screws perform equivalently to the predicate data and does not introduce a new "worst case" implant within the current CapLOX II® / TowerLOX® MIS Pedicle Screw System
Conclusion	The devices associated with this line extension are the same as the previously cleared CapLOX II®/TowerLOX® Pedicle Screw System. There are no changes in the intended use, indications, technological characteristics and principles of operation in comparison to the predicate devices. The proposed modifications raise no new types of safety or effectiveness concerns. The overall technology characteristics lead to the conclusion that the devices under the line extension are substantially equivalent to the predicate devices.