



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Captiva Spine
% Mr. Kenneth C. Maxwell II
Empirical Consulting, LLC
4628 Northpark Drive
Colorado Springs, Colorado 80918

June 26, 2015

Re: K151116
Trade/Device Name: CapLOX II/TowerLOX Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNH, MNI
Dated: June 5, 2015
Received: June 8, 2015

Dear Mr. Maxwell:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K151116

Device Name

CapLOX II/TowerLOX Pedicle Screw System

Indications for Use (Describe)

The CapLOX II/TowerLOX 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, pseudoarthrosis and failed previous fusion.

In addition, when used as a pedicle screw fixation system, the CapLOX II/TowerLOX 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”

510(K) SUMMARY

Submitter's Name:	Captiva Spine
Submitter's Address:	967 N Alternate A1A Ste 1 Jupiter, FL 33477
Submitter's Telephone:	877-772-5571
Contact Person:	Kenneth C. Maxwell Empirical Testing Corp. 719.291.6874
Date Summary was Prepared:	24 April 2015
Trade or Proprietary Name:	CapLOX II/TowerLOX Pedicle Screw System
Common or Usual Name:	Pedicle Screw System
Classification:	Class II per 21 CFR §888.3070
Product Code:	MNI, MNH
Classification Panel:	Division of Orthopedic Devices

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The CapLOX II/TowerLOX Pedicle Screw System is an implant device made from a titanium alloy Ti-6Al-4V ELI. It is to be implanted from the posterior approach. The screws are available in diameters from 4.9-8.0mm and in lengths from 30-100mm. Rods are available in 5.5mm diameter in lengths from 30-600mm and in an array of configurations including, straight and pre-lordosed configurations. The system includes set screws, pedicle screws, and rods along with the associated instrumentation to complete the procedure and implant construct.

INDICATIONS FOR USE

The CapLOX II/TowerLOX 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, pseudoarthrosis and failed previous fusion.

In addition, when used as a pedicle screw fixation system, the CapLOX II/TowerLOX 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.

TECHNICAL CHARACTERISTICS

CapLOX II/TowerLOX Pedicle Screw System is made from titanium alloy that conforms to ASTM F136, and no material changes are being proposed as part of this submission. The subject

and 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

The additions to the system include the following implants and instruments:

- Modular extended tab (tower) pedicle screw head assembly
- Instrumentation and rotating rods to facilitate rod insertion when using tower pedicle screw head assembly

Table 5-1 Predicate Devices

510k Number	Trade or Proprietary or Model Name	Manufacturer	Type
K131538	CapLOX II/TowerLOX Pedicle Screw System	Captiva Spine	Primary

CONCLUSION

The subject modified is CapLOX II/TowerLOX Pedicle Screw System very similar to previously cleared CapLOX II/TowerLOX Pedicle Screw System. The subject CapLOX II/TowerLOX Pedicle Screw System has similar intended uses, indications, technological characteristics, and principles of operation as the predicate devices. The modifications raise no new types of safety or effectiveness questions. The overall technology characteristics lead to the conclusion that the CapLOX II/TowerLOX Pedicle Screw System is substantially equivalent to the predicate devices.