# 510(k) Summary

**Submitter:** Captiva Spine
967 Alt A1A Suite 1
Jupiter, FL 33477
Phone: 877-772-5571
Fax: 866-318-322

**Contact Person:** John Sanders
Consultant
QualiReg Resources LLC
2361 NW 105th Ln
Sunrise, FL 33322
Phone: 954-993-5581
email: johnsanders@qualireg.com

**Date Prepared:** February 28, 2011

**Trade Name:** Captiva Spine FuseLox Cervical IBF System

**Classification** Class II

**Name and Number:** Intervertebral Body Fusion Device
21 CFR 888.3080

**Product Code:** ODP

**Predicate Device(s):** The subject device is substantially equivalent to the following devices:
K092794 Transcorp ACIF
K081730 Alphatec Novel Spinal Spacer System

**Device Description:** The Captiva Spine FuseLox Cervical IBF System includes various size implants manufactured from implant grade PEEK conforming to ASTM F2026-08. The implant is hollow to allow for autogenous bone graft material. The implant is provided non-sterile.

**Intended Use:** The Captiva Spine FuseLox Cervical IBF System 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. Captiva Spine FuseLox implants are used to facilitate fusion in the cervical spine and are placed via an anterior approach at the C3 to C7 disc levels using autogenous 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.

**Performance Data:** Indicates subject device is substantially equivalent to predicates.

**Conclusion:** The documentation provided demonstrates that the Captiva Spine FuseLox Cervical IBF System is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Captiva Spine, Inc.
% QualiReg Resources LLC
Mr. John Sanders
2361 NW 105th Lane
Sunrise, Florida 33322

MAR 25 2011

Re: K110585
Trade/Device Name: Captiva Spine FuseLox Cervical IBF System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP
Dated: February 28, 2011
Received: March 01, 2011

Dear Mr. Sanders:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use Statement

510(k) Number: K110585

Device Name: Captiva Spine FuseLox Cervical IBF System

Indications for Use:

The Captiva Spine FuseLox Cervical IBF System 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. Captiva Spine FuseLox implants are used to facilitate fusion in the cervical spine and are placed via an anterior approach at the C3 to C7 disc levels using autogenous 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.

| Prescription Use X (Part 21 CFR 801 Subpart D) | AND/OR | Over-The-Counter Use _____ (21 CFR 801 Subpart C) |
|---|---|---|

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K110585