5. 510(k) Summary

JUN 19 2013

Submitted By:	CoAlign Innovations 2684 Middlefield Road, Suite A Redwood City, CA 94063
Establishment Registration Number:	10030843
Contact Person: (Submission Prepared by)	Justin Eggleton Musculoskeletal Clinical & Regulatory Advisers, LLC 1331 H Street NW, 12th Floor Washington, DC 20005 202.552.5800
Date Prepared:	May 14, 2013
Device Trade Name:	AccuLIF® XL Cage
Manufacturer:	CoAlign Innovations, Inc. 2684 Middlefield Road, Suite A Redwood City, CA 94063
Common Name:	Spinal intervertebral body fixation orthosis
Classification:	21 CFR §888.3080
Class:	II
Product Code:	MAX

Device Description:
The AccuLIF XL Cage acts as a spacer to maintain proper intervertebral spacing and angulation following discectomy. The AccuLIF XL Cage is manufactured from Ti6Al4V ELI) as per ASTM F136-08, Stainless Steel (316 LVM) as per ASTM F138-08, PEEK (Invibio Optima LT1) as per ASTM F2026-07, and Silicone Rubber (MED-4870). The device is inserted in unexpanded state with an articulating delivery handle and expanded in-situ to the required height via 2 hydraulic cylinder and piston arrangement using a hydraulic system comprising disposable flexible expansion tubing set and inflation syringe. The device locks in 1mm increments as it expands. The AccuLIF XL Cage comes in 6 to 9mm, 8 to 12mm and 10 to 16mm sizes. The device has fixation ridges on the top and bottom surface. In addition each size comes in 8 foot prints 1) 45mm length x 18mm width, 2) 45mm length x 22mm width, 3) 50mm length x 18mm width, 4) 50mm

length x 22mm width, 5) 55mm length x 18mm width, 6) 55mm length x 22mm width 7) 60mm length x 18mm width, and 8) 60mm length x 22mm width. It also has a graft opening window which extends from the bottom surface to the top surface. The device has a proximal boss which has a threaded connection port for connecting to the inserter and a fluid port for transporting the expansion fluid

Indications For Use:
Intervertebral Body Fusion Device: The CoAlign Innovations AccuLIF XL Cage is indicated for intervertebral body fusion with autogenous bone graft material in patients with degenerative disc disease (DDD) at one level or two contiguous levels from L2 to S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). These patients should be skeletally mature and have completed six months of non-operative treatment.

The CoAlign Innovations AccuLIF XL Cage is always to be used with supplemental internal spinal fixation. Additionally, the CoAlign Innovations AccuLIF XL Cage is to be used with autogenous bone graft.

Identification of Predicates

- AccuLIF XL Cage (K130194)
- AccuLIF TL-PEEK Cage (K123281)

Summary of Technological Characteristics
AccuLIF XL Cages are expandable spacers made from Titanium-6AL-4V ELI alloy that conforms to ASTM F136 and PEEK (Invibio Optima LT1) that conforms to ASTM F2026-07. 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
- Expansion mechanism
- Structural support mechanism

Discussion of Testing:
The following non-clinical tests were conducted:

- Surgical technique validation, conducted in the same manner as the predicate surgical technique validation.

Conclusions:
The subject and predicate devices share the same indications for use, design, function, and materials of manufacture. The predicate device testing represented a worst case such that any minor differences do not impact device performance as compared to the predicates. The AccuLIF XL Cage was shown to be substantially equivalent to the AccuLIF XL (K130194), the AccuLIF TL-PEEK Cage (K123281).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

June 19, 2013

CoAlign Innovations, Incorporated
% Musculoskeletal Clinical Regulatory Advisers, LLC
Mr. Justin Eggleton
Director, Spine Regulatory Affairs
1331 H Street North West, 12th Floor
Washington, District of Columbia 20005

Re: K131443
Trade/Device Name: AccuLIF XL Cage
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: May 14, 2013
Received: May 20, 2013

Dear Mr. Eggleton:

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 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. 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,

For Erin D Keith

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

Enclosure

4. Indications for Use

510(k) Number (if known): K131443

Device Name: AccuLIF XL Cage

Intervertebral Body Fusion Device: The CoAlign Innovations AccuLIF XL Cage is indicated for intervertebral body fusion with autogenous bone graft material in patients with degenerative disc disease (DDD) at one level or two contiguous levels from L2 to S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). These patients should be skeletally mature and have completed six months of non-operative treatment.

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

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton E. Dmitriev, PhD
Division of Orthopedic Devices