



Food and Drug Administration  
10903 New Hampshire Avenue  
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October 15, 2014

Cogent Spine, LLC  
% Mr. Jude Paganelli  
Cor Medical Ventures, LLC  
101 North Acacia Avenue, Suite 106  
Solana Beach, California 92075

Re: K142193  
Trade/Device Name: Cogent Med-LIF XL  
Regulation Number: 21 CFR 888.3080  
Regulation Name: Intervertebral body fusion device  
Regulatory Class: Class II  
Product Code: MAX  
Dated: September 15, 2014  
Received: September 16, 2014

Dear Mr. Paganelli:

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,

**Ronald P. Jean -S** for

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)

K142193

Device Name

Cogent Mcd-LIF XL

### Indications for Use (Describe)

The Cogent Mcd-LIF XL is indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These devices are intended for intervertebral body fusion, and are intended to be used with supplemental fixation instrumentation which has been cleared by the FDA for use in the lumbar spine.

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.\***

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# SECTION 5

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## 510(K) SUMMARY

### SUBMITTER:

#### Submitted By:

**Company Name:** Cogent Spine  
**Address:** 101 N. Acacia, Suite 106  
Solana Beach, CA 92075  
**Telephone:** (858) 774-7891

**CONTACT PERSON:** Jude Paganelli

**DATE PREPARED:** July 30, 2014

**TRADE NAME:** Cogent Med-LIF XL

**COMMON NAME:** Intervertebral Body Fusion Device

**CLASSIFICATION NAME:** Intervertebral Body Fusion Device (21 CFR 888.3080)

**PRODUCT CODE:** MAX

### SUBSTANTIALLY EQUIVALENT TO:

The Cogent Med-LIF XL is substantially equivalent to the predicate, Cogent Med-LIF System (K132738) in all facets including: indications, technology, method of use and performance.

### DESCRIPTION of the DEVICE:

The Cogent Med-LIF XL includes additional sizes to the Cogent Med-LIF system. The Cogent Med-LIF XL is an interbody fusion device intended to stabilize the spinal segment to promote fusion. The Cogent Med-LIF XL consists of two PEEK spacers with axial voids to contain bone graft material, a titanium linkage that connects the PEEK spacers, angular anti-migration teeth, and tantalum x-ray markers.

The Cogent Med-LIF XL is available in various sizes to accommodate varying patient anatomy. The implants come in two lordotic options, 0° (parallel) and 6° (lordotic). The parallel implants are available in heights ranging from 8mm to 16mm and the lordotic implants are available in heights ranging from 10mm to 16mm. All implants are 15mm wide and are available in three lengths; 28, 30 and 32mm.

The Cogent Med-LIF XL implants may be inserted via an open or minimally invasive approach and may be placed as a single implant or as two units bilaterally in the same intervertebral space.

The Cogent Med-LIF XL implants are non-sterile and are to be sterilized by the end user.

#### **MATERIALS:**

The Cogent Med-LIF XL is manufactured from polyetheretherketone (PEEK) as per ASTM F2026 and contains titanium alloy (Ti-6Al-4V) per ASTM F1472 and tantalum per ASTM F560.

#### **INDICATIONS FOR USE:**

The Cogent Med-LIF XL is indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These devices are intended for intervertebral body fusion, and are intended to be used with supplemental fixation instrumentation which has been cleared by the FDA for use in the lumbar spine.

#### **NON-CLINICAL TEST SUMMARY:**

Cogent Spine conducted the following bench tests:

ASTM F2077

- Static Shear Compression
- Dynamic Shear Compression

In summary, mechanical and non-clinical testing of the Cogent Med-LIF XL device indicated no new risks and demonstrated substantial equivalence in performance compared to a legally marketed predicate.

#### **CLINICAL TEST SUMMARY:**

No clinical studies were performed.

**CONCLUSIONS:**

The Cogent Med-LIF XL device has shown to be substantially equivalent to a legally marketed predicate based on indications for use, technological characteristics, performance testing and comparison to predicate devices.