APR 15 2014

SECTION 5
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: April 15, 2014

TRADE NAME: Cogent Med-LIF

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 is substantially equivalent to the predicates in all facets including: indications, technology, method of use and performance. The predicate devices for the Cogent Med-LIF system are:

Eisertech PLIF Cage (K113478)
Stryker Spine AVS PL PEEK Spacers (K073470)
Custom Spine Pathway Avid (K090566)
Sapphire Medical Group A-Wedge Anterior Interbody System (K121693)

DESCRIPTION of the DEVICE:

The Cogent Med-LIF is an interbody fusion device intended to stabilize the spinal segment to promote fusion. The Cogent Med-LIF 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 is available in various sizes to accommodate varying patient anatomy. The implants come in two lordotic options, 0° (parallel)

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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 10mm wide and are available in three lengths; 20, 25 and 30mm.

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

MATERIALS:

The Cogent Med-LIF 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 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.

PERFORMANCE TESTING:

Cogent Spine conducted the following bench tests:

ASTM F2077

- Static Axial Compression
- Dynamic Axial Compression
- Static Shear Compression
- Dynamic Shear Compression

ASTM F2267

- Subsidence

Expulsion Testing per ASTM Draft Standard F04.25.02.02

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Additionally, Cogent Spine conducted a cadaveric implantation study to confirm autogenous bone graft can be adequately delivered when compared to a legally marketed predicate.

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

CONCLUSIONS:

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

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

April 15, 2014

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

Re: K132738
Trade/Device Name: Cogent Med-LIF
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: February 12, 2013
Received: March 21, 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 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" (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 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,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K132738

Device Name
Cogent Med-LIF

Indications for Use *(Describe)*

The Cogent Med-LIF 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)*

Anton E. Dmitriev, PhD

Division of Orthopedic Devices

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

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