



JAN 11 2013

## **510(k) Summary**

as required by section 807.92(c).

### **TLS 5.0 Interbody Cage**

**K121254**

Camber Spine Technologies

401 Yankee Court

Newtown Square, PA 19073

Daniel A Pontecorvo

President

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Submitted 1/7/13

Submitter:	Camber Spine Technology 401 Yankee Court Newtown Square, PA 19073
Contact Person	Daniel A Pontecorvo President Phone: (484) 420-4671 Email: delvalsyn@comcast.net

Trade Name	Camber Spine Technologies TLS 5.0 Interbody Cage
Common Name	TLS 5.0 Interbody Cage
Device Class	Class II
Classification Name and Number	Intervertebral Fusion Device With Bone Graft, Lumbar 21 CFR 888.3080
Classification Panel:	Orthopedic
Product Code	MAX
Reason for 510k	New Device
Predicate Devices	Corelink Foundation Cage (K 073440), Stryker AVS PL (K093704) & K2M Aleutian (K113138)
Device Description	<p>Camber Spine Technologies, TLS 5.0 Interbody Cage is a device for interbody fusion of the anterior column of the spine. These cages are hollow so that bone can grow through the device, fusing the adjacent bony surfaces.</p> <p>Camber Spine Technologies, TLS 5.0 Interbody Cage is a hollow device with texture on two opposing convex sides, and is offered in various lengths, widths, heights and shapes. Camber Spine designed the Camber Spine Technologies, TLS 5.0 Interbody Cage to be placed through a transforaminal or posterior approach and to address vertebrae in the lumbosacral region of the spine.</p>

Intended Use	<p>The Camber Spine Technologies TLS 5.0 Interbody Cage is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. DDD is defined as discogenic pain 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). Camber Spine Technologies TLS 5.0 Interbody Cage is to be used with autologous bone graft and implanted via an open transforaminal or posterior approach.</p> <p>Camber Spine Technologies TLS 5.0 Interbody Cage implants are to be used with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.</p>
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Materials:	<p>The implant is manufactured from ASTM2026 Solvay Zeniva ZA-500 implant grade Polyetheretherketone (PEEK)</p>
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Statement of Technological Comparison	<p>Camber Spine Technologies TLS 5.0 Interbody Cage and its predicate devices have the same indications for use, similar design, and test results. Both devices are manufactured using materials with a long history of use in orthopaedic implants.</p>
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<p>Nonclinical Test Summary</p>	<p>The following tests were performed to demonstrate that the Camber Spine Technologies TLS 5.0 Interbody Cage is substantially equivalent to other predicate devices.</p> <ul style="list-style-type: none"> <li>• Static and Dynamic Compression Test per ASTM F2077</li> <li>• Static and Dynamic Compression Shear ASTM F2077</li> <li>• Subsidence Test per ASTM F2267</li> <li>• Wear Debris ASTM F2077 and ASTM F1877</li> <li>• Static Expulsion Test</li> </ul> <p>The results of these studies showed that the Camber Spine Technologies TLS 5.0 Interbody Cage met the acceptance criteria.</p>
<p>Clinical Test Summary</p>	<p>No clinical tests were performed.</p>

Sterilization Information	
<p>Implants</p>	<p>The Implant will be shipped non-sterile and will be autoclaveable, validation testing of the process was conducted (using the half-cycle method) to a Sterility Assurance Level (SAL) of 10<sup>-6</sup> per ISO 17665.</p>
<p>Instruments and Case</p>	<p>The instrument and case will be shipped non-sterile and will be autoclaveable, validation testing of the process was conducted (using the half-cycle method) to a Sterility Assurance Level (SAL) of 10<sup>-6</sup> per ISO 17665.</p>

<p>Conclusion</p>	<p>The TLS 5.0 Interbody Cage is substantially equivalent to its predicate devices. This conclusion is based upon the fact the Lumbar Cage and its predicate devices have the same indications for use, have a similar design, and similar test results.</p>
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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

Camber Spine Technologies  
% Mr. Daniel A. Pontecorvo  
President  
401 Yankee Court  
Newtown Square, Pennsylvania 19073

Letter dated: January 11, 2013

Re: K121254

Trade/Device Name: Camber Spine Technologies TLS 5.0 Interbody Cage  
Regulation Number: 21 CFR 888.3080  
Regulation Name: Intervertebral body fusion device  
Regulatory Class: Class II  
Product Code: MAX  
Dated: November 26, 2012  
Received: November 28, 2012

Dear Mr. Pontecorvo:

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**

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: K121254

Device Name: **Camber Spine Technologies TLS 5.0 Interbody Cage**

### Indications:

The Camber Spine Technologies TLS 5.0 Interbody Cage is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. DDD is defined as discogenic pain 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). Camber Spine Technologies TLS 5.0 Interbody Cage is to be used with autologous bone graft and implanted via an open transforaminal or posterior approach.

Camber Spine Technologies TLS 5.0 Interbody Cage implants are to be used with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

Prescription Use  AND/OR Over-the-counter

(Part 21 CFR 801 Subpart D)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

**Colin O'Neill**

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(Division Sign-Off)

Division of Orthopedic Devices

510(k) Number: K121254