



Food and Drug Administration  
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DeGen Medical  
% Linda Braddon, Ph.D.  
President/CEO  
Secure BioMed Evaluations  
7828 Hickory Flat Highway, Suite 120  
Woodstock, Georgia 30188

December 15, 2015

Re: K151496

Trade/Device Name: Latitude-C Cervical Interbody Spacer System  
Regulation Number: 21 CFR 888.3080  
Regulation Name: Intervertebral body fusion device  
Regulatory Class: Class II  
Product Code: ODP  
Dated: November 12, 2015  
Received: November 16, 2015

Dear Dr. Braddon:

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,

**Mark N. Melkerson -S**

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)

K151496

Device Name

Latitude-C Cervical Interbody Spacer System

Indications for Use (Describe)

The Latitude-C Interbody Spacer is indicated for spinal fusion procedures at one level in the cervical spine (C2-T1), in skeletally mature patients with degenerative disc disease. Degenerative disc disease is defined as neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies.

The Latitude-C Interbody Spacer is intended for use with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft and supplemental fixation, eg. Hyper-C Anterior Cervical Plate System.

Patients must have undergone a regimen of at least six weeks of non-operative treatment prior to being treated with the Latitude-C Interbody Spacer in the cervical 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)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

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In accordance with 21 CFR 807.87 (h) and 21 CFR 807.92, the 510(k) summary for the DeGen Medical LATITUDE-C is provided below.

<i>Date Summary Prepared</i>	November 12, 2015
<i>Manufacturer/Distributor/Sponsor</i>	DeGen Medical 1321-C North Cashua Drive Florence, SC 29501 Phone 877-240-7838 Fax 843-407-0545
<b>510(k) Contact</b>	Secure BioMed Evaluations Linda Braddon, Ph.D. 7828 Hickory Flat Highway Suite 120 Woodstock, GA 30188 770-837-2681 LGB@SecureBME.com
<i>Trade Name</i>	<b>Latitude-C Cervical Interbody Spacer System</b> Latitude-C PEEK Cervical Interbody Spacer Latitude-C Porous Ti Cervical Interbody Spacer Latitude-C HA PEEK Cervical Interbody Spacer Latitude-C CFR Cervical Interbody Spacer Latitude-C Ti Cervical Interbody Spacer
<i>Common Name</i>	Intervertebral body fusion device
<i>Code –Classification</i>	ODP 21 CFR 888.3080 : Class II
<i>Primary Predicate</i>	K142152 – CONSTRUX Mini PEEK Spacer System
<i>Reference Devices</i>	K133967 - Aurora Spine Interbody Fusion System K142026 - Arena-C® HA PEEK Cervical Intervertebral Body Fusion Device K103488 – Depuy Spine Bengal Spine System P980048 - BAK/Cervical Interbody Fusion System
<i>Device Description</i>	<i>DeGen Medical Latitude-C Cervical Interbody Spacer</i> is a cervical interbody fusion device for anterior cervical fusion procedures. The <i>Latitude-C spacer</i> has teeth on its superior and inferior surfaces to prevent migration. The Latitude-C spacer comes in 5 different size footprints, and different heights ranging from 5mm to 14mm.

<p><b>Indications for Use</b></p>	<p><i>The Latitude-C Interbody Spacer is indicated for spinal fusion procedures at one level in the cervical spine (C2-T1), in skeletally mature patients with degenerative disc disease. Degenerative disc disease is defined as neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies.</i></p> <p><i>The Latitude-C Interbody Spacer is intended for use with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft and supplemental fixation, eg. Hyper-C Anterior Cervical Plate System.</i></p> <p><i>Patients must have undergone a regimen of at least six weeks of non-operative treatment prior to being treated with the Latitude-C Interbody Spacer in the cervical spine.</i></p>
<p><b>Technological Characteristics</b></p>	<p>As was established in this submission, the subject Latitude-C Cervical Interbody Spacer is substantially equivalent to other predicate devices cleared by the FDA for commercial distribution in the United States. The subject device was shown to be substantially equivalent and has the same technological characteristics to its predicate devices through comparison in areas including design, intended use, material composition, function, and range of sizes.</p>
<p><b>Non-Clinical Performance Testing Conclusion</b></p>	<p>Non-clinical testing was performed to demonstrate the DeGen Medical Latitude-C Cervical Interbody Spacer is substantially equivalent to other predicate devices in accordance with “Guidance for Industry and FDA Staff, Guidance for Spinal System 510(k)s”, May 3, 2004 and Class II Special Controls Guidance Document: Intervertebral Body Fusion Device, June 12, 2007.</p> <p>The following tests were performed:</p> <ul style="list-style-type: none"> <li>• Static and dynamic compression testing per ASTM F2077</li> <li>• Static and dynamic torsion testing per ASTM F2077</li> <li>• Subsidence testing via ASTM F2267</li> <li>• Expulsion Testing</li> <li>• Wear testing per ASTM F1877</li> </ul> <p>Additional tests were included on the coating:</p> <ul style="list-style-type: none"> <li>• Static Tensile Strength</li> <li>• Static Shear Strength</li> <li>• Abrasion Resistance</li> <li>• Shear Fatigue</li> </ul> <p>The results of these studies show the subject DeGen Medical Latitude-C Cervical Interbody Spacer meets or exceeds the performance of the predicate devices, and the device was therefore found to be substantially equivalent.</p>



<p><i>Substantial Equivalence Summary (Conclusion)</i></p>	<p>Based on the indications for use, technological characteristics, performance testing, and comparison to predicate devices, the subject DeGen Medical Latitude-C Cervical Interbody Spacer has been shown to be substantially equivalent to legally marketed predicate devices.</p>
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