



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

July 28, 2015

Re: K150759
Trade/Device Name: Hyper-C Anterior Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: June 25, 2015
Received: July 1, 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" (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 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

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 on last page.

510(k) Number (if known)

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Device Name

Hyper-C Anterior Cervical Plate System

Indications for Use (Describe)

The DeGen Medical Hyper-C Anterior Cervical Plate system is intended for use as an aid in cervical spinal fusion and is intended for unilateral fixation. The Hyper-C Anterior Cervical Plate system is intended for anterior intervertebral screw fixation of the cervical spine at levels C2 to T1. The system is indicated for temporary stabilization of the anterior spine during the development of cervical spine fusions in patients with following indications:

- *Degenerative Disc Disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies)*
- *Spinal Stenosis*
- *Trauma (i.e. fracture or dislocation)*
- *Deformity or curvatures (including scoliosis, kyphosis, or lordosis)*
- *Spinal Tumors*
- *Pseudoarthrosis or failed previous fusion*
- *Spondylolisthesis*
- *Decompression of the spine following total or partial cervical vertebrectomy*

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)

510(k) Summary of Safety and Effectiveness

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

<i>Date Summary Prepared</i>	June 25, 2015
<i>Manufacturer/Distributor/Sponsor</i>	DeGen Medical 1321-C North Cashua Drive Florence, SC 29501 Phone 877-240-7838 Fax 843-407-0545
510(k) Contact	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>	Hyper-C Anterior Cervical Plate System
<i>Common Name</i>	Spinal intervertebral body fixation orthosis
<i>Code –Classification</i>	KWQ 21 CFR 888.3060 : Class II
<i>Primary Predicate</i>	K142237 Stryker Aviator Anterior Cervical Plating System
<i>Reference Devices</i>	K083562 Stryker Aviator Anterior Cervical Plating System K971883 Synthes Small Stature Anterior Cervical Locking Plate System K030866, K031276, K926453, K945700 Synthes CSLP K052292 X-Spine Spider Cervical Plate K01387, K121658 Orthofix Hallmark Anterior Cervical Plate System
<i>Device Description</i>	The DeGen Medical Hyper-C Anterior Cervical Plate Systems consists of cervical plates and bone screws. All implants are intended to provide stabilization of the cervical vertebrae. The HACP provides anterior fixation from either fixed or variable angle construct in self-tapping or self-drilling bone screw options. The system is provided in both sterile and non-sterile versions. The system is constructed from Titanium alloy (Ti-6Al-4V ELI) per ASTM F136.

<i>Indications for Use</i>	<p><i>The DeGen Medical Hyper-C Anterior Cervical Plate system is intended for use as an aid in cervical spinal fusion and is intended for unilateral fixation. The Hyper-C Anterior Cervical Plate system is intended for anterior intervertebral screw fixation of the cervical spine at levels C2 to T1. The system is indicated for temporary stabilization of the anterior spine during the development of cervical spine fusions in patients with following indications:</i></p> <ul style="list-style-type: none"> • <i>Degenerative Disc Disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies)</i> • <i>Spinal Stenosis</i> • <i>Trauma (i.e. fracture or dislocation)</i> • <i>Deformity or curvatures (including scoliosis, kyphosis, or lordosis)</i> • <i>Spinal Tumors</i> • <i>Pseudoarthrosis or failed previous fusion</i> • <i>Spondylolisthesis</i> • <i>Decompression of the spine following total or partial cervical vertebrectomy</i>
<i>Technological Characteristics</i>	<p>As was established in this submission, the subject Hyper-C Anterior Cervical Plate System (HACP) 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>
<i>Non-Clinical Performance Testing Conclusion</i>	<p>Non-clinical testing was performed to demonstrate the DeGen Medical Hyper-C Anterior Cervical Plate System (HACP) 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. The following tests were performed:</p> <ul style="list-style-type: none"> • Static and dynamic compression testing per ASTM F1717 • Static torsion testing per ASTM F1717 • Screw strength via ASTM F543 • Push-out testing for Locking Screws <p>The results of these studies show the subject DeGen Medical Hyper-C Anterior Cervical Plate System (HACP) meets or exceeds the performance of the predicate devices, and the device was therefore found to be substantially equivalent.</p>
<i>Substantial Equivalence Summary (Conclusion)</i>	<p>Based on the indications for use, technological characteristics, performance testing, and comparison to predicate devices, the subject DeGen Medical Hyper-C Anterior Cervical Plate System (HACP) has been shown to be substantially equivalent to legally marketed predicate devices.</p>