DeGen Medical INC  
℅ Linda Braddon  
President/CEO  
Secure BioMed Evaluations  
7828 Hickory Flat Highway Suite 120  
Woodstock, Georgia 30188  

Re: K191786  
Trade/Device Name: Cyclops™ 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: July 31, 2019  
Received: August 1, 2019

Dear Linda 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.


For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Colin O'Neill -
for RPJ

Ronald Jean, Ph.D.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure
510(k) Number *(if known)*
K191786

Device Name
Cyclops™ Anterior Cervical Plate System

Indications for Use *(Describe)*
The DeGen Medical Cyclops™ Anterior Cervical Plate System is intended for use as an aid in cervical spinal fusion and is intended for unilateral fixation. The Cyclops™ 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 spinal 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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### 510(k) Summary of Safety and Effectiveness

In accordance with 21 CFR 807.87 (h) and 21 CRF 807.92, the 510(k) summary for the DeGen Medical Cyclops Anterior Cervical Plate (CACP) is provided below.

<table>
<thead>
<tr>
<th><strong>Date</strong></th>
<th>July 2, 2019</th>
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| **Sponsor**    | DeGen Medical, Inc.  
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  
Regulatory@SecureBME.com |
| **Trade Name** | Cyclops™ Anterior Cervical Plate System |
| **Common Name** | Spinal Intervertebral Body Fixation Orthosis |
| **Code – Classification** | KWQ  
21 CFR 888.3060: Class II |
| **Primary Predicate** | K150759 Hyper-C Anterior Cervical Plate System |
| **Additional Predicates** | K971883 Synthes Small Stature Anterior Cervical Locking Plate System  
K030866, K031276, K926453, K945700 Synthes CSLP  
K052292 X-Spine Spider Cervical Plate  
K013877, K121658 Orthofix Hallmark Anterior Cervical Plate System  
K080646, K133518 Biomet Maxan Anterior Cervical Plate System |
| **Device Description** | The DeGen Medical Cyclops™ Anterior Cervical Plate Systems (CACP) consists of cervical plates and bone screws. All implants are intended to provide stabilization of the cervical vertebrae. The CACP provides anterior fixation from either fixed or variable angle construct in self-tapping or self-drilling bone screw options. The system is provided non-sterile and is constructed from Titanium alloy (Ti-6Al-4V ELI) per ASTM F136. |
| **Indications for Use** | The DeGen Medical Cyclops™ Anterior Cervical Plate system is intended for use as an aid in cervical spinal fusion and is intended for unilateral fixation. The Cyclops™ 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 spinal following total or partial cervical vertebrectomy |
| **Technological Characteristics** | As was established in this submission, the subject Cyclops™ Anterior Cervical Plate System (CACP) 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. |
| **Non-Clinical Performance Testing Conclusion** | Non-clinical testing was performed to demonstrate the DeGen Medical Cyclops™ Anterior Cervical Plate System (CACP) 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:  
- Static and dynamic compression testing per ASTM F1717  
- Static torsion testing per ASTM F1717  
- Screw strength via ASTM F543  
- Push-out testing for Screws  
The results of these studies show the subject DeGen Medical Cyclops™ Anterior Cervical Plate System (CACP) meets or exceeds the performance of the predicate devices, and the device was therefore found to be substantially equivalent. |
| **Substantial Equivalence Summary (Conclusion)** | Based on the indications for use, technological characteristics, performance testing, and comparison to predicate devices, the subject DeGen Medical Cyclops™ Anterior Cervical Plate System (CACP) has been shown to be substantially equivalent to legally marketed predicate devices. |