January 7, 2022

DeGen Medical
% Linda Braddon
CEO
Secure BioMed Evaluations
7828 Hickory Flat Highway Suite 120
Woodstock, Georgia 30188

Re: K213901
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: December 13, 2021
Received: December 14, 2021

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.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

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, M.B.E.
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213901

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.

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SPECIAL 510(k): DeGen Medical
Cyclops™ Anterior Cervical Plate System
1321-C North Cashua Drive
Florence, SC 29501

510(k) SUMMARY: Cyclops™ Anterior Cervical Plate System

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

Date Prepared	December 13, 2021
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
Product Code Classification	KWQ 21 CFR 888.3060, Class II
Primary Predicate	K191786 Cyclops™ Anterior Cervical Plate System
Additional Predicate	K150759 DeGen Medical Hyper-C 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. The purpose of this submission is to add additional two-level plate lengths to the Cyclops™ Anterior Cervical Plate System.

Indications for Use Statement	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 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	A risk review was conducted on existing verification and validation data for the Cyclops™ Anterior Cervical Plate System regarding the additional two-level plates. The results of this risk review indicated that there would be no impacts to safety or effectiveness of the system by including this device.
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.