November 13, 2019

HUVEXEL Co., Ltd
℅ Milan George
Vice President, R&D
Dio Medical Corporation
2000 Campus Lane, Suite 200
Eagleville, Pennsylvania 19403

Re: K191477
Trade/Device Name: AEON-C™ Stand Alone System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVE
Dated: October 15, 2019
Received: October 16, 2019

Dear Mr. George:

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,

Brent Showalter, Ph.D.
Assistant Director (Acting)
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: 06/30/2020

See PRA Statement below.

510(k) Number
K191477

Device Name
AEON-C™ Stand Alone System

Indications for Use *(Describe)*

The AEON-C™ Stand Alone System is a stand-alone anterior cervical intervertebral fusion device indicated for use in skeletally mature patients with degenerative disc disease (DDD) with accompanying radicular symptoms at one or two contiguous levels from C2-T1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. The AEON-C™ Stand Alone System should be packed with autograft and/or allograft comprised of cancellous, cortical and/or corticocancellous bone graft and implanted with an anterior approach.

Patients should receive at least six (6) weeks of non-operative treatment prior to treatment with a cervical intervertebral fusion device.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) SUMMARY

HUVEXEL Co., Ltd's
AEON-C™ Stand Alone System

Sponsor:	Manufacturer	HUVEXEL Co., Ltd. 101-105 Megacenter, SKn Technopark 124 Sagimakgol-ro, Jungwon-gu Seongnam-si Gyeonggi-do, South Korea
	Official Contact Phone: Fax:	Milan George 267-737-9496 x102 847-795-1079
	Date:	October 15, 2019
Device Name:	AEON-C™ Stand Alone System	
Common Name:	Intervertebral Body Fusion Device, Cervical	
Classification Name:	Intervertebral fusion device with integrated fixation, cervical	
Classification Number:	Class II	
Product Code/Classification:	OVE	
Description:	The AEON-C™ Stand Alone System includes PEEK interbodies and titanium interbodies, which utilize a titanium alloy locking mechanism that is either integrated in an anterior fixation plate or within the interbody. Both PEEK interbodies and titanium interbodies, with or without fixation plates, are to be anchored to patient anatomy via two (2) titanium alloy bone screws. The implant design includes multiple footprints, heights and lordosis options and the screw design includes multiple diameters and lengths, to fit a variety of patient anatomies.	
Intended Use:	The AEON-C™ Stand Alone System is a stand-alone anterior cervical intervertebral fusion device indicated for use in skeletally mature patients with degenerative disc disease (DDD) with accompanying radicular symptoms at one or two contiguous levels from C2-T1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. The AEON-C™ Stand Alone System should be packed	

	with autograft and/or allograft comprised of cancellous, cortical and/or corticocancellous bone graft and implanted with an anterior approach.
Performance Data:	Non-clinical testing was performed to demonstrate that the subject AEON-C™ Stand Alone System is substantially equivalent to the predicate device. The following testing was performed in accordance with the ASTM F2077 and ASTM F2267: - Static & Dynamic compression - Static & Dynamic compression shear - Static & Dynamic Torsion - Subsidence - Expulsion The nonclinical tests demonstrate that the AEON-C™ Stand Alone System is as safe, as effective, and performs as well as or better than the legally marketed predicate devices.
Predicate Device:	Primary predicate: Globus Medical Inc. – COALITION® and COALITION AGX® (K083389 and K173115) Additional predicates: Spinal Elements, Inc.– Vertu, and Vertu Ti-Bond (K122771 and K181837), and K2M, Inc.- CASCADIA™ Interbody System (K160125)
Reference Device:	K111362 – Rexious Spinal Fixation System
Technological Characteristics	The AEON-C™ Stand Alone System was shown to be substantially equivalent and has equivalent technological characteristics to its predicate and reference devices through comparison in areas including design, labeling/intended use, material composition, function, range of sizes, and packaging.
Performance and SE Determination:	The AEON-C™ Stand Alone System has been demonstrated to be substantially equivalent to the predicate system(s) with respect to technical characteristics, performance, and intended use. The information provided within this premarket notification supports substantial equivalence of the subject device to the predicate device(s) and demonstrates that the device is as safe, as effective, and performs as well as or better than the legally marketed device predicate.