December 20, 2022

Dio Medical Inc
Milan George
VP of R&D
2100 Campus LaneSuite 100
East Norriton, Pennsylvania 19403

Re: K223140
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: September 30, 2022
Received: October 4, 2022

Dear Milan 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,

Katherine D. Kavlock -S

for
Brent Showalter, 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

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)*
K223140

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.

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510(k) SUMMARY

Dio Medical
AEON-C™ Stand Alone System

Sponsor:	Manufacturer:	Dio Medical Corp. 2100 Campus Lane, Suite 100 East Norriton, PA 19403
	Official Contact: Email: Phone:	Milan George mgeorge@dio-us.com 1-877-394-5407 ext.102
Date Prepared:	September 30, 2022	
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:	21 CFR 888.3080	
Product Code/ Classification:	OVE, Class II	
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.	

	Patients should receive at least six (6) weeks of non-operative treatment prior to treatment with a cervical intervertebral fusion device.
Predicate Device:	Primary predicate: Huvexel Co. Ltd. - AEON-C™ Stand Alone System (K191477)
Substantial Equivalence:	The AEON-C™ Stand Alone System is identical to the predicate device and is as safe and effective as the Huvexel - AEON-C™ Stand Alone System. The Subject device has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. There are no technological differences between the Subject device and its predicate devices resulting in no K191477 issues of safety or effectiveness. Thus, the Dio Medical- AEON-C™ Stand Alone System is identical/substantially equivalent to the predicates.
Performance Data:	The subject and predicate devices are identical and therefore, no performance testing is required. Submission is only transferring name of a system that has already been cleared under K191477. No testing is required.
Conclusion:	The Dio Medical AEON-C™ Stand Alone System has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. Thus, the subject device is identical/substantially equivalent to the predicate device.