March 9, 2023

Dio Medical Corp.
Milan George
VP of R&D
2100 Campus Lane, Suite 100
East Norriton, Pennsylvania 19403

Re: K223790
Trade/Device Name: Huvex Interspinous Fusion System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal Interlaminal Fixation Orthosis
Regulatory Class: Class II
Product Code: PEK
Dated: March 2, 2023
Received: March 3, 2023

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,

Colin O'neill -S

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)*
K223790

Device Name
Huvex Interspinous Fusion System

Indications for Use *(Describe)*

The Huvex Interspinous Fusion System is a single-level, posterior, non-pedicle supplemental fixation device intended for use in the lumbar spine (T1-S1) as an adjunct to fusion in skeletally mature patients. It is intended for plate fixation/attachment to the Huvex Interspinous Fusion System for the purpose of achieving supplemental fusion in the following conditions: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), and/or tumor. The Huvex Interspinous Fusion System is intended for use at one level, in conjunction with autogenous bone graft, and not intended for stand-alone use.

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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510(k) SUMMARY

Dio Medical
Huvex Interspinous Fusion System

Sponsor:	Manufacturer:	Dio Medical Corp. 2100 Campus Lane, Suite 100 East Norriton, PA 19403
	Official Contact:	Milan George
	Email:	mgeorge@dio-us.com
	Phone:	1-877-394-5407 ext.102

Date Prepared:	December 16, 2022
Device Name:	Huvex Interspinous Fusion System
Common Name:	Spinous Process Plate
Classification Name:	Spinal interlaminal fixation orthosis
Classification Number:	21 CFR 888.3050
Product Code/ Classification:	PEK, class II

Description:

The HUVEX Interspinous Fusion System consists of a left plate, a right plate, pin, bolt, inner cap, center bar, and set screw. Each of these components is provided in several sizes to allow for the construction of five different HUVEX Interspinous Fusion implant sizes. The left plate is provided assembled with the poly axial bar. The bar has a bone graft window to allow fusion between spinous process. Poly axial bar is also designed to fit the anatomical characteristics of the spinous process. The right plate is designed to be combined with left plate fixed to spinous process. Right plate contains a set screw to lock the right plate to the poly axial bar. The HUVEX Interspinous Fusion System components are supplied non-sterile, are single use and are fabricated from titanium alloy (Ti-6AI-4V ELI) that conforms to ASTM F 136.

In addition to the implants a set of reusable surgical instruments are provided. Both implant and instruments have trays that are used for handling and storage.

Indications For Use:	The Huvex Interspinous Fusion System is a single-level, posterior, non-pedicle supplemental fixation device intended for use in the lumbar spine (T1-S1) as an adjunct to fusion in skeletally mature patients. It is intended for plate fixation/attachment to the Huvex Interspinous Fusion System for the purpose of achieving supplemental fusion in the following conditions: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), and/or tumor. The Huvex Interspinous Fusion System is intended for use at one level, in conjunction with autogenous bone graft, and not intended for stand-alone use.
Predicate Device:	Primary predicate: Huvexel Co. Ltd. - Huvex Interspinous Fusion System (K162849)
Substantial Equivalence:	The Huvex Interspinous Fusion System is identical to the predicate device and is as safe and effective as the Huvexel - Huvex Interspinous Fusion 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 new issues of safety or effectiveness. Thus, the Dio Medical- Huvex Interspinous Fusion 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 K162849. No testing is required.
Conclusion:	The Dio Medical Huvex Interspinous Fusion 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.