October 5, 2022

Dio Medical Corporation
Milan George
Vice President of R&D
2100 Campus Lane, Suite 100
East Norriton, Pennsylvania 19403

Re: K222515
Trade/Device Name: FaSet Fixation System
Regulatory Class: Unclassified
Product Code: MRW
Dated: August 18, 2022
Received: August 19, 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,

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)*
K222515

Device Name
FaSet Fixation System

Indications for Use *(Describe)*

The FaSet Fixation System is intended to stabilize the spine as an aid to fusion through bilateral immobilization of facet joints. The Facet Screw System is indicated for posterior surgical treatment with or without bone graft at single or multiple levels from C2 to S1 (inclusive). For transfacet fixation, the screws are inserted posteriorly through the superior side of the facet, across the facet joint, and into the pedicle. For translaminar facet fixation, the screws are inserted posteriorly through the lateral aspect of the spinous process, through the lamina, through the superior side of the facet, across the facet joint, and into the pedicle. The FaSet Fixation System is indicated for treatment for any or all of the following:

- Spondylolisthesis
- Pseudoarthrosis or failed previous fusions which are symptomatic, or which may cause secondary instability or deformity
- Spondylolysis
- Degenerative Disk Disease (DDD) as defined by back pain of discogenic origin with degeneration of disk confirmed by history and radiographic studies and/or degenerative disease of the facets with instability
- Trauma including spinal fractures and/or dislocations.

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
FaSet Fixation 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:	August 18, 2022	
Device Name:	FaSet Fixation System	
Common Name:	System, Facet Screw Spinal Device	
Classification Name:	Unclassified	
Classification Number:	N/A	
Product Code/ Classification:	MRW, Unclassified	
Description:	The FaSet Fixation System consist of permanent implant devices manufactured from titanium or titanium alloy (Ti-6Al-4V ELI) as specified in ASTM F67, and F136. Various sizes and lengths of these implants are available to accommodate patient anatomy. The device is intended to provide mechanical support and stability to the implanted level until biologic fusion is achieved.	
Intended Use:	The FaSet Fixation System is intended to stabilize the spine as an aid to fusion through bilateral immobilization of facet joints. The Facet Screw System is indicated for posterior surgical treatment with or without bone graft at single or multiple levels from C2 to S1 (inclusive). For transfacet fixation, the screws are inserted posteriorly through the superior side of the facet, across the facet joint, and into the pedicle. For translaminar facet fixation, the screws are inserted posteriorly through the lateral aspect of the spinous process, through the lamina, through the superior side of the facet, across the facet joint, and into the pedicle. The FaSet Fixation System is indicated for treatment for any or all of the following:	

	- Spondylolisthesis - Pseudoarthrosis or failed previous fusions which are symptomatic, or which may cause secondary instability or deformity - Spondylolysis - Degenerative Disk Disease (DDD) as defined by back pain of discogenic origin with degeneration of disk confirmed by history and radiographic studies and/or degenerative disease of the facets with instability - Trauma including spinal fractures and/or dislocations.
Predicate Device:	Primary predicate: Huvexel Co. Ltd. - FaSet Fixation System (K180729)
Substantial Equivalence:	The FaSet Fixation System is identical to the predicate device and is as safe and effective as the Huvexel - FaSet Fixation 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- FaSet Fixation 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 K180729. No testing is required.
Conclusion:	The Dio Medical FaSet Fixation 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.