October 25, 2022

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

Re: K222415
Trade/Device Name: Rexious Spinal Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB, KWP
Dated: August 5, 2022
Received: August 10, 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)*
K222415

Device Name
Rexious Spinal Fixation System

Indications for Use *(Describe)*
The Rexious Spinal Fixation System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative disc disease; spondylolisthesis; fracture; dislocation; scoliosis; kyphosis; spinal tumor; and failed previous fusion (pseudarthrosis).

The Rexious Spinal Fixation System is intended for use as a posterior, noncervical, non-pedicle system indicated for 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); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

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
Rexious Spinal 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 5, 2022	
Device Name: Common Name:	Rexious Spinal Fixation System Pedicle Screw Spinal Fixation System	
Classification Name:	Thoracolumbosacral Pedicle Screw System	
Classification Number:	21 CFR 888.3070	
Product Code/ Classification:	NKB, KWP, Class II	
Description:	The Rexious Spinal Fixation System is a top-loading multiple component, posterior spinal fixation system which consists of fixation system which consists of pedicle screws, rods, set screws, connectors, hooks, and transverse (cross) linking mechanisms. The Rexious Spinal Fixation System will allow surgeons to build a spinal implant construct to stabilize and promote spinal fusion. The Rexious implant components are supplied non-sterile, single use and fabricated from titanium or titanium alloy (Ti-6Al-4V ELI) as specified in ASTM F67, F136, and F1295 and from Cobalt-Chromium-Molybdenum (CoCr) as specified in ASTM F1537. Various sizes of these implants are available.	
Indications for Use:	The Rexious Spinal Fixation System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative disc disease;	

	spondylolisthesis; fracture; dislocation; scoliosis; kyphosis; spinal tumor; and failed previous fusion (pseudarthrosis). The Rexious Spinal Fixation System is intended for use as a posterior, noncervical, non-pedicle system indicated for 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); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.
Predicate Device:	Primary predicate: Huvexel Co. Ltd. - Rexious Spinal Fixation System (K173131) Additional predicates: Huvexel Co. Ltd. : Rexious Hook System (K113324) Huvexel Co. Ltd. - Rexious Spinal Fixation System (K100765, K111362)
Substantial Equivalence:	The Rexious Spinal Fixation System is identical to the predicate device, the Huvexel - Rexious Spinal Fixation System and Rexious Hook 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 Rexious Spinal 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 K100765, K113324, K111362, and K173131. No testing is required.
Conclusion:	The Dio Medical Rexious Spinal 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.