December 8, 2017

Huvexel Co., Ltd.
% Mr. Milan George
Senior Director
Dio Medical Corporation
8770 W Bryn Mawr Avenue, Suite 1250
Chicago, Illinois 60631

Re: K173131
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
Dated: November 9, 2017
Received: November 13, 2017

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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 *(if known)*
K173131

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).

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

HUVEXEL Co., Ltd's
CoCr Rods & Additional Implants

Sponsor:	Manufacturer	HUVEXEL Co., Ltd. 101-105 Megacenter, SK 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:	November 9, 2017
Device Name:	Rexious Spinal Fixation System	
Common Name:	Pedicle Screw Spinal Fixation System	
Classification Name:	Thoracolumbosacral Pedicle Screw System	
Classification Number:	21 CFR 888.3070	
Product Code/Classification:	NKB, class II	
Description:	The Rexious Spinal Fixation System is a top-loading multiple component, posterior spinal fixation system which consists fixation system which consists of pedicle screws, rods, set screws, connectors, 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.	
Device Modification & Technological Characteristics:	The purpose of this 510(k) submission is to introduce additional lengths of rods, additional material for rods, additional screw sizes, and additional transverse connector sizes. The modified system has the same intended use and fundamental scientific technology as the previously-cleared system.	

Intended 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).
Performance Data:	The addition of components to the system did not introduce a new worst case construct as evaluated based on an engineering analysis. Static and Dynamic compression bend tests per ASTM F1717 were also performed.
Predicate Device:	Primary predicate: Rexious Spinal Fixation System (K111362) Additional predicate: Globus Medical Inc. - CoCr rods (K100788)
Performance and SE Determination:	The CoCr rods and additional Rexious implants have 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).