Huvexel Co., Ltd
% Milan George
Senior R&D Director
Dio Medical Corporation
8770 W Bryn Mawr Ave.
Ste. 1250
Chicago, Illinois 60631

November 30, 2017

Re: K173099
Trade/Device Name: Fortis and Hana Anterior Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: September 28, 2017
Received: September 29, 2017

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. 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,

Mark N. Melkerson -S

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)*

Device Name
Fortis and Hana Anterior Cervical Plate System

Indications for Use *(Describe)*
Fortis and Hana Anterior Cervical Plate System is intended for anterior fixation to the cervical spine C2-C7. The specific clinical indications include:

degenerative disc disease (DDD) (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, deformities or 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

HUVEXEL Co., Ltd's
FORTIS and HANA Anterior Cervical Plate System

Sponsor:	Manufacturer:	HUVEXEL Co., Ltd. 101-105 Megacenter, SK Technopark 124 Sagimakgol-ro, Jungwon-gu Seongnam-si Gyeonggi-do, South Korea
	Official Contact: Email: Phone: Fax:	Milan George mgeorge@dio-us.com 267-737-9496 x102 847-795-1079
Date Prepared:		November 30, 2017
Device Name:	FORTIS and HANA Anterior Cervical Plate System	
Common Name:	Anterior Cervical Plate System	
Classification Name:	Spinal Intervertebral Body Fixation Orthosis	
Classification Number:	21 CFR 888.3060	
Product Code/Classification:	KWQ, class II	
Description:	The FORTIS and HANA Anterior Cervical Plate System consists of a variety of shapes and sizes of Main Plates, screw, lock-plate and the associated instruments. The lock-plate is pre-assembled to the main plate and designed to prevent screws from backing out. Each component is subjected to a color anodizing process to differentiate the screw type and diameter and to make the surgical process easy. The plates range in length to accommodate one and two-level procedures for HANA and one, two, three, and four level procedures for FORTIS. Main plate is available from 13mm to 46mm for HANA and 10mm to 112mm for FORTIS. Screws are available in lengths from 12mm to 20mm for HANA and 10mm to 20mm in 2mm increments for FORTIS. The screws have either a 4.5mm or 5.1mm diameter for HANA and 4.0mm or 4.5mm diameter for FORTIS. They are fixed self-tapping, variable self-tapping screw, fixed self-drilling screw, variable self-drilling. The FORTIS and HANA Anterior Cervical Plate System components are supplied non-sterile, are single use and are fabricated from titanium allow (Ti-6Al-4V ELI) that conforms to ASTM F136.	

Intended Use:	The FORTIS and HANA Anterior Cervical Plate System is intended for anterior fixation to the cervical spine C2-C7. The specific clinical indications include: degenerative disc disease (DDD) (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis, and failed previous fusion.
Performance Data:	Mechanical testing (Static compression bending, Dynamic compression bending, and Static torsion test) in accordance with the ASTM 1717 was performed.
Predicate Device:	Primary predicate: Huvexel - Rex Anterior Cervical Plate System (K121862) Additional predicate: Globus Medical – VIP Anterior Cervical Plate System (K081391), Synthes Spine – Synthes Anterior CSLP System (K000742), EBI – EBI Anterior Cervical Plate System (K001794) and Aesculap – Aesculap ABC Cervical Plating System (K974706)
Performance and SE Determination:	The FORTIS and HANA Anterior Cervical Plate System has 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).