October 18, 2022

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

Re: K222572
Trade/Device Name: FORTIS and HANA Anterior Cervical Plate System, Rex Anterior Cervical Plate System, and BALTEUM™ & BALTEUM-ONE™ Lumbar Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: August 24, 2022
Received: August 25, 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)*
K222572

Device Name
FORTIS and HANA Anterior Cervical Plate System, Rex Anterior Cervical Plate System, and BALTEUM™ & BALTEUM-ONE™ Lumbar Plate System

Indications for Use *(Describe)*

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.

The REX Anterior Cervical Plate System is intended for anterior fixation to the cervical spine. 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.

The BALTEUM™ and BALTEUM-ONE™ Lumbar Plate Systems are intended for use via a lateral or anterolateral surgical approach above the bifurcation of the great vessels in the treatment of thoracic and thoracolumbar (T1 – L5) spine instability or via the anterior surgical approach, below the bifurcation of the great vessels in the treatment of lumbar and lumbosacral (L1 – S1) spine instability as a result of fracture (including dislocation and subluxation), tumor, degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), scoliosis, kyphosis, lordosis, spinal stenosis, or a failed previous spine surgery. The device is intended as a temporary fixation device until fusion is achieved.

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.

review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services

Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA)
Staff *PRAStaff@fda.hhs.gov*

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

Dio Medical
FORTIS and HANA Anterior Cervical Plate System, Rex Anterior Cervical Plate System, and BALTEUM™ & BALTEUM-ONE™ Lumbar Plate 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 24, 2022	
Device Names:	FORTIS and HANA Anterior Cervical Plate System, Rex Anterior Cervical Plate System, and BALTEUM™ & BALTEUM-ONE™ Lumbar Plate System	
Common Name:	Anterior Cervical Plate System, Spinal Implants, Spinal Fixation Device, Lumbar 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 alloy (Ti-6Al-4V ELI) that conforms to ASTM F136.

Rex Cervical Plate System consists of a variety of shapes and sizes of Main Plates, screw, sub-plate, rivets and the associated instruments. The sub-plate is pre-assembled to the main plate and designed to prevent screws from backing out using the elastic behavior during the screw insertion. The rivets are also pre-assembled to the main plate and designed to assemble the sub-plate to the main plate firmly. 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, two, three, and four level procedures. Main plates are available from 20mm to 110mm. Screws are available in lengths from 10mm to 20mm in 2mm increments. The screws have either a 3.5mm or 4.0mm diameter. They are fixed self-tapping, Variable self-tapping screw, fixed self-drilling screw, Variable self-drilling and are available in lengths ranging from 10mm to 20mm in 2mm increments. The Rex Cervical Plate System components are supplied non-sterile, are single use and are fabricated from titanium alloy (Ti-6Al-4V ELI) that conforms to ASTM F 136.

The BALTEUM™ & BALTEUM-ONE™ Lumbar Plate System consists of non-sterile, single use, rigid plates and bone screws of varying sizes and lengths to fit the anatomical needs of a wide variety of patients. The plate attaches by means of screws to the vertebral body of the thoracolumbar spine (T1-L5) either through an antero-lateral, or lateral approach and to the lumbar/lumbosacral spine (L1-S1) through an anterior approach. The system includes instrumentation which assists in the surgical implantation of the device.

Indications for 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.

	The REX Anterior Cervical Plate System is intended for anterior fixation to the cervical spine. 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. The BALTEUM™ and BALTEUM-ONE™ Lumbar Plate Systems are intended for use via a lateral or anterolateral surgical approach above the bifurcation of the great vessels in the treatment of thoracic and thoracolumbar (T1-L5) spine instability or via the anterior surgical approach, below the bifurcation of the great vessels in the treatment of lumbar and lumbosacral (L1-S1) spine instability as a result of fracture (including dislocation and subluxation), tumor, degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), scoliosis, kyphosis, lordosis, spinal stenosis, or a failed previous spine surgery. The device is intended as a temporary fixation device until fusion is achieved.
Predicate Device:	Primary Predicate: Huvexel Co. Ltd. - FORTIS and HANA Anterior Cervical Plate System (K173099) Additional predicates: Huvexel Co. Ltd. : Rex Anterior Cervical Plate System (K121862) Rex Anterior Cervical Plate System, and Huvexel Co. Ltd. : BALTEUM™ & BALTEUM-ONE™ Lumbar Plate System(K200846, K213820)
Substantial Equivalence:	The FORTIS and HANA Anterior Cervical Plate System, Rex Anterior Cervical Plate System, and BALTEUM™ & BALTEUM-ONE™ Lumbar Plate System are identical to the predicate devices and are as safe and effective as the Huvexel - FORTIS and HANA Anterior Cervical Plate System, Rex Anterior Cervical Plate System, and BALTEUM™ & BALTEUM-ONE™ Lumbar Plate 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 their predicate devices resulting in no new issues of safety or effectiveness. Thus, the Dio Medical - FORTIS and HANA Anterior

	Cervical Plate System, Rex Anterior Cervical Plate System, and BALTEUM™ & BALTEUM-ONE™ Lumbar Plate System are 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 K121862, K173099, K200846, and K213820. No testing is required.
Conclusion:	The Dio Medical- FORTIS and HANA Anterior Cervical Plate System, Rex Anterior Cervical Plate System, and BALTEUM™ & BALTEUM-ONE™ Lumbar Plate System have the same intended uses and similar indications, technological characteristics, and principles of operation as their predicate device. Thus, the subject devices are identical/substantially equivalent to the predicate devices.