



March 25, 2022

Huvexel Co., Ltd
% Milan George
Vice President, R&D
Dio Medical Corporation
2100 Campus Lane, Suite 100
East Norriton, Pennsylvania 19403

Re: K213820

Trade/Device Name: 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: December 23, 2021
Received: December 27, 2021

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,

for 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

Indications for Use

510(k) Number (if known)
K213820

Device Name
BALTEUM - ONE™ Lumbar Plate System

Indications for Use (Describe)

The BALTEUM™ and BALTEUM - ONE™ Lumbar Plate System 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.

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510(k) SUMMARY

HUVEXEL Co., Ltd's BALTEUM - ONE™ Lumbar Plate System

Sponsor: Manufacturer HUVEXEL Co., Ltd.
**101-105 Megacenter, SKn Technopark
124 Sagimakgol-ro, Jungwon-gu
Seongnam-si
Gyeonggi-do, South Korea**

Official Contact Milan George
Phone: 877-394-5407x102

Date: December 7, 2021

Device Name: BALTEUM - ONE™ Lumbar Plate System

Common Name: Anterior Thoracolumbosacral Plate

Classification Name: Spinal intervertebral body fixation orthosis, 21 CFR 888.3060

Classification Number: Class II

Product Code/Classification: KWQ

Description: The 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.

Intended Use: 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.

Performance Data: Non-clinical testing was performed to demonstrate that the subject BALTEUM - ONE™ Lumbar Plate System is substantially equivalent to the predicate device. The following testing was performed in accordance with the ASTM F1717:

- Static compression
- Dynamic compression
- Static Torsion

The nonclinical tests demonstrate that the BALTEUM - ONE™ Lumbar Plate System is substantially equivalent to the legally marketed predicate devices.

Predicate Device: Primary predicate: BALTEUM™ Lumbar Plate System (K200846) - HUVEXEL Co., Ltd
Additional predicates: Globus Medical – Plymouth™ Thoracolumbar Plate System (K120092), Globus Medical – TRUSS™ Thoracolumbar Plate System (K092108), NuVasive Lateral Plate System (K091071) and Globus Medical - REVERE™ Stabilization System (K061202)

Technological Characteristics The BALTEUM - ONE™ Lumbar Plate System was shown to be substantially equivalent and has equivalent technological characteristics to its predicate and reference devices through comparison in areas including design, labeling/intended use, material composition, function, range of sizes, and packaging.

Performance and SE Determination: The BALTEUM - ONE™ Lumbar Plate System 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).