February 17, 2023

GBS Commonwealth Co., Ltd.
Jimmy Kim
C-309, Woolim Lion's Valley, 168, Gasan Digital 1-ro
Geumcheon-gu, Seoul 08507
South Korea

Re: K213755
Trade/Device Name: Peridot-PT Anterior Cervical Intervertebral body fusion System, Peridot-PT Intervertebral body fusion system
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP, MAX
Dated: January 13, 2023
Received: January 17, 2023

Dear Jimmy Kim:

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,

Brent Showalter -S

Brent Showalter, Ph.D.
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)*

K213755

Device Name

Peridot-PT Anterior Cervical Intervertebral body fusion System, Peridot-PT Intervertebral body fusion system

Indications for Use *(Describe)*

Peridot-PT Anterior Cervical Intervertebral body fusion System

The Peridot-PT Anterior Cervical Intervertebral body fusion system is intended for use for anterior cervical interbody fusion in skeletally mature patients with cervical disc degeneration and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at one or multiple contiguous levels from C2-T1. The Peridot-PT Anterior Cervical Intervertebral body fusion system is also to be used with supplemental fixation systems that have been cleared for use in the cervical spine.

The Peridot-PT Anterior Cervical Intervertebral body fusion system is designed for use with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion.

Peridot-PT Intervertebral body fusion system

The Peridot-PT Intervertebral body fusion system is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). This device is to be used with autogenous bone graft. The Peridot-PT Intervertebral body fusion system is to be used with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

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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SUMMARY

The following summary is being submitted as required by 21 CFR 807.92(a):

1. Device Identification

Submitter: GBS Commonwealth Co., Ltd.
#C-309, 168 Gasan Digital 1-ro, Geumcheon-Gu Seoul, South Korea
Phone. 82-2-6925-4469
e-mail: Jimmy.kim@gbscommonwealth.com

Contact Person: Jimmy Kim
Date prepared November 26, 2021

Trade Name	Peridot-PT Anterior Cervical Intervertebral body fusion System, Peridot-PT Intervertebral body fusion system
Regulatory Class	Class II
Classification Name	Intervertebral body fusion device (21 CFR 888.3080)
Panel	Orthopedic
Product Code	ODP, MAX

2. Purpose of 510(k)

The GBS Commonwealth Co. Ltd., here by submits this submission: for Initial product Introduction of Peridot-PT Anterior Cervical Intervertebral body fusion system and Peridot-PT Intervertebral body fusion system

3. Predicate or legally marketed devices which are substantially equivalent

Primary Predicate Device : K201605 EIT Cellular Titanium ALIF,TLIF,LLIF,T/PLIF Cage

1) Additional Predicate Device : K192026 Peridot Interverbral body fusion system

K202872 Prase PEEK Anterior Cervical Interbody Spacer

4. Description of the Device

The Peridot-PT Cages are a comprehensive portfolio of 3D-printed porous titanium interbody devices intended to stabilize the spinal segment, restore intervertebral height and to facilitate interbody fusion in the cervical (C2-T1) and lumbar spine (L2-S1).

Designed to treat cervical and lumbar degenerative disc disease, the platform consists of the Cervical, Transforaminal (TLIF), Direct Lateral (LLIF), Anterior (ALIF) and Transforaminal / Posterior Lumbar (T/PLIF) systems. Each system features a full breadth of sizes, footprints, heights and angles.

The devices are intended to be used with supplemental spinal fixation, either applied anterior or posterior (e.g. using posterior pedicle screws, anterior plate system or anterior screw and rod system).

The implant cages are supplied sterilized.

The Peridot-PT Cages are made from Ti-6Al-4V ELI conforming to ASTM F3001 with an additive manufacturing process (Selective Laser Melting). The design contains solid structures and porous structures. The hollow geometry of the implants allows them to be packed with autogenous bone graft, and two of the systems allow for the cages to be packed with allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft.

The hyperlordotic lumbar cages (>20 degree) the form of supplemental fixation should be an anterior plate system.

5. Indication for Use

Peridot-PT Anterior Cervical Intervertebral body fusion System

The Peridot-PT Anterior Cervical Intervertebral body fusion system is intended for use for anterior cervical interbody fusion in skeletally mature patients with cervical disc degeneration and/or cervical spinal instability, as confirmed by imaging studies (radiographs, CT, MRI), that results in radiculopathy, myelopathy, and/or pain at one or multiple contiguous levels from C2-T1. The Peridot-PT Anterior Cervical Intervertebral body fusion system is also to be used with supplemental fixation systems that have been cleared for use in the cervical spine.

The Peridot-PT Anterior Cervical Intervertebral body fusion system is designed for use with autogenous and/or allogeneic bone graft comprised of cancellous and/or

corticocancellous bone graft to facilitate fusion.

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Peridot-PT Intervertebral body fusion system is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s).This device is to be used with autogenous bone graft. Peridot-PT Intervertebral body fusion system is to be used with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

6. Comparison of the technological characteristics of the subject and predicate devices

Peridot-PT Anterior Cervical Intervertebral body fusion system and Peridot–PT Intervertebral body fusion system are considered substantially equivalent to the primary predicate EIT Cellular Titanium ALIF, TLIF, LLIF T/PLIF Cage K201605 and additional predicate devices. They are similar in design, material, scientific technologies and indications for use.

7. Performance Testing

The worst-case devices were tested in static compression, static compression-shear, static torsion, fatigue compression, fatigue compression-shear, fatigue torsion (ASTM F2077) and subsidence test (ASTM F2267).

8. Conclusion

Based on the information provided in this premarket notification of GBS Commonwealth Co., Ltd. concludes that Peridot-PT Anterior Cervical Intervertebral body fusion system and Peridot-PT Intervertebral body fusion system are substantially equivalent to predicate devices.