March 15, 2022

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

Re: K213980
Trade/Device Name: Peridot Spinal Interbody System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP, MAX
Dated: December 16, 2021
Received: December 20, 2021

Dear Mr. 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, 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)*
K213980

Device Name
Peridot Spinal Interbody System

Indications for Use *(Describe)*

Peridot Spinal Interbody System - Cervical

The Peridot Cervical Spinal Interbody System are intended for intervertebral body fusion devices in skeletally mature patients for the treatment of 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 more contiguous levels from C2-T1. These patients should have had at least six weeks of nonoperative treatment.

The Peridot Cervical Spinal Interbody system are to be used with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft to faciliate fusion and in combination with supplemental fixation indicated for cervical fusion procedures.

Peridot Spinal Interbody System - Lumbar

The Peridot Lumbar Spinal Interbody system are 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 Lumbar Spinal Interbody system are 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.
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Phone. 82-2-6925-4469
e-mail: Jimmy.kim@gbscommonwealth.com

Contact Person: Jimmy Kim
Date prepared December, 16, 2021

Trade Name	Peridot Spinal Interbody 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 the Peridot Spinal Interbody System.

The Purpose of this 510(k) submission is to combine the existing 510(k) clearance system (K192026 and K202872). The Peridot Spinal Interbody System has the same intended use and fundamental scientific technology as the previously cleared system (K192026 and K202872).

3. Predicate or legally marketed devices which are substantially equivalent

- Primary Predicate Device : K192026 Peridot Intervertebral body fusion system

- Additional Predicate Device : K202872 Prase PEEK Anterior Cervical Interbody Spacer
K163491 NuVasive CoRoent Small Interbody System

4. Description of the Device

Peridot Spinal Interbody System

This product is intervertebral body fixation devices intended for use as an aid in spinal fusion. This product is made from PEEK as per ASTM F2026 and Tantalum marker as per ASTM F560.

X-ray markers system on the cages permits the identification of cage position and allows post-operative assessment.

The devices are available in a variety of different sizes and heights to match more closely the patient's anatomy. The ends of the implants have machined teeth which are designed to engage with the vertebral body end plates. The devices are supplied non-sterile.

The device is supplied with their specific instrument. The specific instrument is supplied dedicated tray and non-sterile. The device must be used in combination with the dedicated instrument supplied.

Peridot Spinal Interbody System

This product is intervertebral body fixation devices intended for use as an aid in spinal fixation. This product is made from PEEK as per ASTM F2026 and Tantalum marker as per ASTM F560. And some cage holders are made of titanium alloy as per ASTM F136.

X-ray markers system on the cages permits the identification of cage position and allows post-operative assessment.

The devices are available in a variety of different sizes and heights to match more closely the patient's anatomy. The ends of the implants have machined teeth which are designed to engage with the vertebral body end plates. The devices are supplied non-sterile.

The devices consist of cages differentiated by their approach, with varying dimensions and ancillary products for placement of the cages.

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

The device must be used in combination with the dedicated instrument supplied.

5. Indication for Use

Peridot Spinal Interbody System

The Peridot Cervical Spinal Interbody System are intended for intervertebral body fusion devices in skeletally mature patients for the treatment of 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 more contiguous levels from C2-T1. These patients should have had at least six weeks of nonoperative treatment. The Peridot Cervical Spinal Interbody system are to be used with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft to faciliate fusion and in combination with supplemental fixation indicated for cervical fusion procedures.

Peridot Spinal Interbody System

The Peridot Lumbar Spinal Interbody system are 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 Lumbar Spinal Interbody system are 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

The Peridot Spinal Interbody System are the same as the legally marketed devices 'Peridot Intervertebral body fusion System (K192026)' and 'Prase PEEK Anterior Cervical Interbody spacer (K202872)'. It has the same design, material, scientific technologies and indications for use.

7. Performance Testing

The Peridot Spinal Interbody System is the same as the legally marketed devices ‘K192026’ and ‘K202872’. So, the performance test was proved by the previous legally marketed devices performance test.

8. Conclusion

The Peridot Spinal Interbody System has been demonstrated to be same to the predicate device with respect to technical characteristics, performance, and intended use.

The information provided within this premarket notification supports same as the subject device to the predicate devices.