



October 13, 2023

GBS Commonwealth Co., Ltd.
Mr. Jimmy Kim
#C-309, 168 Gasan Digital 1-ro
Geumcheon-Gu, Seoul 08507
South Korea

Re: K232822

Trade/Device Name: Peridot-TD Spacer system (The Peridot-TD Intervertebral body fusion system),
Anterior cervical interbody fusion - ACIF (The Peridot-TD Anterior Cervical
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: September 7, 2023

Received: September 13, 2023

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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

Indications for Use

510(k) Number (if known)

K232822

Device Name

Anterior cervical interbody fusion - ACIF (The Peridot-TD Anterior Cervical Intervertebral body fusion system), Peridot-TD Spacer system (The Peridot-TD Intervertebral body fusion system)

Indications for Use (Describe)

Anterior cervical interbody fusion - ACIF (The Peridot-TD Anterior Cervical Intervertebral body fusion system)

The Peridot-TD 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-TD 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.

These patients should have had at least six weeks of nonoperative treatment.

The Peridot-TD 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-TD Spacer system (The Peridot-TD Intervertebral body fusion system)

The Peridot-TD 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-TD Intervertebral body fusion system is to be used with supplemental fixation. Patients should have at least six (6) months of nonoperative 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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 South Korea
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 e-mail: Jimmy.kim@gbscommonwealth.com

Contact Person: Jimmy Kim
Date prepared September, 7, 2023

Trade Name	Peridot-TD Spacer system (The Peridot-TD Intervertebral body fusion system) and Anterior cervical interbody fusion - ACIF (The Peridot-TD Anterior Cervical 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:
 Additional models with sterilization methods added to the previously cleared 510(k), K230708. (Add user sterilization (Steam sterilization) from existing gamma sterilization)

3. Predicate or legally marketed devices which are substantially equivalent

- Primary Predicate Device : K230708 Peridot-TD Spacer system (The Peridot-TD Intervertebral body fusion system) and Anterior cervical interbody fusion - ACIF (The Peridot-TD Anterior Cervical Intervertebral body fusion system) / GBS Commonwealth

4. Description of the Device

The Peridot-TD Cages are intervertebral fusion device manufactured from poly-ether-ether-ketone (PEEK) per ASTM F2026 with tantalum markers per ASTM F560 for radiographic visualization. The Peridot-TD Cages have a 0.5 ~ 1.0micron thick surface coat of commercially pure (CP) titanium per ASTM F67.

And some cages holders are made of titanium alloy as per ASTM F136.

The Peridot-TD Cages 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), 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 screw and rod system, anterior plate and screw system, or lateral plate and screw system).

The devices are to be sterilized by gamma radiation per ISO 11137 or provided non-sterile. The non-sterile devices are to be sterilized by steam sterilization per ISO 17665.

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

The device is supplied with its specific instruments. The device must be used in combination with the dedicated instruments supplied. The specific instruments are supplied dedicated tray and non-sterile.

5. Indication for Use

Anterior cervical interbody fusion - ACIF (The Peridot-TD Anterior Cervical

Intervertebral body fusion system)

The Peridot-TD 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-TD 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-TD 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-TD Spacer system (The Peridot-TD Intervertebral body fusion system)

The Peridot-TD 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-TD Intervertebral body fusion system is to be used with supplemental fixation. Patients should have at least six (6) months of nonoperative treatment prior to treatment with an intervertebral cage.

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

The subject device has the same design, material, scientific technologies and indications for use as previously cleared 510(k), K230708. Only models have been added according to the addition of sterilization method.

7. Performance Testing

The worst-case devices were tested.

1) Anterior cervical interbody fusion - ACIF (The Peridot-TD Anterior Cervical Intervertebral body fusion system)

- Static Compression (ASTM F2077)
- Static Torsion (ASTM F2077)
- Fatigue Compression (ASTM F2077)
- Fatigue Torsion (ASTM F2077)
- Subsidence (ASTM F2267)
- Static Tensile (ASTM F1147)
- Static Shear (ASTM F1044)
- Fatigue Shear (ASTM F1160)
- Wear (ASTM F1978)

2) Peridot-TD Spacer system (The Peridot-TD Intervertebral body fusion system)

- Static Compression (ASTM F2077)
- Static Compression-shear (ASTM F2077)
- Fatigue Compression (ASTM F2077)
- Fatigue Compression-shear (ASTM F2077)
- Subsidence (ASTM F2267)
- Static Tensile (ASTM F1147)
- Static Shear (ASTM F1044)
- Fatigue Shear (ASTM F1160)
- Wear (ASTM F1978)

8. Conclusion

Based on the information provided in this premarket notification of GBS Commonwealth Co., Ltd. concludes that Anterior cervical interbody fusion – ACIF and Peridot-TD Spacer are substantially equivalent to predicate devices.