



November 7, 2023

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

Re: K232292

Trade/Device Name: Peridot-EX Expandable Intervertebral body fusion system  
Regulation Number: 21 CFR 888.3080  
Regulation Name: Intervertebral Body Fusion Device  
Regulatory Class: Class II  
Product Code: 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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Katherine D. Kavlock -S

for

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)  
K232292

Device Name  
Peridot-EX Expandable Intervertebral body fusion system

### Indications for Use (Describe)

The Peridot-EX Expandable 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 and/or allogenic bone graft composed of cancellous and/or corticocancellous bone graft.

The device is intended to be used with supplemental fixation systems that have been cleared for use in the lumbosacral spine (e.g., posterior pedicle screw and rod systems, anterior plate systems and anterior screw and rod systems).

The Peridot-EX Expandable 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.

Hyperlordotic interbody devices ( $> 20^\circ$  lordosis) must be used with at least anterior supplemental fixation.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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**K232292**  
**510(k) 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  
Phone. 82-2-6925-4469  
e-mail: Jimmy.kim@gbscommonwealth.com

**Contact Person:** Jimmy Kim  
**Date prepared** July, 28, 2023

Trade Name	Peridot-EX Expandable Intervertebral body fusion system
Regulatory Class	Class II
Classification Name	Intervertebral body fusion device (21 CFR 888.3080)
Panel	Orthopedic
Product Code	MAX

**2. Purpose of 510(k)**

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

**3. Predicate or legally marketed devices which are substantially equivalent**

- Primary Predicate Device : K193258 ProLift Expandable System, Life Spine, Inc.
- Additional Predicate Device : 1) K210800 IO Expandable Lumbar Interbody Fusion system, MiRus, LLC
  - 2) K142498 Magnify and Magnify-S Spacers, Globus Medical, Inc.
  - 3) K222554 EL Capitan Anterior Lumbar Interbody Fusion, Astura Medical
  - 4) K161379 ELSA Spacers, Globus Medical, Inc.
  - 5) K213755 Peridot-PT Intervertebral fusion System, GBS Commonwealth



#### **4. Description of the Device**

The Peridot-EX Expandable Intervertebral body fusion system is various lengths and heights, which can be inserted between two lumbar or lumbosacral vertebral bodies to give support and correction during lumbar interbody fusion surgeries. It is manufactured from titanium alloy (Ti-6Al-4V ELI) as described by ASTM F136 and 3D Printing manufactured from titanium powder (Ti-6Al-4V ELI) as described by ASTM F3001.

The Peridot-EX Expandable Intervertebral body fusion system expands for adjustable lordosis and height to match patient anatomy. The hollow geometry of the implants allows them to be packed with autogenous and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone.

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 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.

All implants are intended for SINGLE USE ONLY and should not be reused under any circumstances.

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

#### **5. Indication for Use**

##### The Peridot-EX Expandable Intervertebral body fusion system

The Peridot-EX Expandable 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 and/or allogenic bone graft composed of cancellous and/or corticocancellous bone graft.

The device is intended to be used with supplemental fixation systems that have been cleared for use in the lumbosacral spine (e.g., posterior pedicle screw and rod systems, anterior plate systems and anterior screw and rod systems).

The Peridot-EX Expandable 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.

Hyperlordotic interbody devices ( $> 20^\circ$  lordosis) must be used with at least anterior supplemental fixation.

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

The Peridot-EX Expandable Intervertebral body fusion system is considered substantially equivalent to the primary predicate device ProLift Expandable System K193258 and additional predicated devices K210800, K142498, K222554, K161379, K213755 and K190762.

They are similar in design, material, scientific technologies and indications for use.

## **7. Performance Testing**

The worst-case devices were tested.

### **1) Peridot-EX Expandable Intervertebral body fusion system**

- Static Compression (ASTM F2077)
- Static Compression-shear (ASTM F2077)
- Static Torsion (ASTM F2077)
- Fatigue Compression (ASTM F2077)
- Fatigue Compression-shear (ASTM F2077)



- Subsidence (ASTM F2267)
- Expulsion (ASTM F-04.25.02.02)

## **8. Conclusion**

Based on the information provided in this premarket notification of GBS Commonwealth Co., Ltd. concludes that Peridot-EX Expandable Intervertebral body fusion system is substantially equivalent to predicate device.