November 26, 2019

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

Re: K192026
Trade/Device Name: Peridot Intervertebral body fusion system
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: October 22, 2019
Received: October 28, 2019

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,

for
Brent Showalter, Ph.D.
Assistant Director (Acting)
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192026

Device Name
Peridot Intervertebral body fusion system

Indications for Use *(Describe)*
Peridot 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 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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510(k) SUMMARY

The following 510(k) 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 July, 25, 2019

Trade Name	Peridot Intervertebral body fusion system
Classification	21 CFR 888.3080 Intervertebral body fusion device, Class II Product Code: MAX

2. Purpose of 510(k)

The GBS Commonwealth Co. Ltd., here by submits this traditional 510(k): for Initial product Introduction of Peridot Intervertebral fusion system.

3. Predicate or legally marketed devices which are substantially equivalent

1) Primary Predicate Device: K151140 LnK Lumbar Interbody Fusion Cage System
2) Additional Predicate device: K092193 Shurfit Interbody device system
K153783 SpaceVision OLIF
K110927 MectaLIF Oblique
K161379 ELSA Spacers

4. Description of the Device

The Peridot Intervertebral Body Fusion System is intervertebral body fixation devices intended for use as an aid in spinal fixation. The Peridot Intervertebral fusion system 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 device is 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 device is supplied non-sterile.

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

The device is supplied with their specific instrument. The specific instrument is supplied dedicated tray and non-sterile. The device and instrument are supplied separately.

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

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

5. Indication for Use

Peridot 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 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

The Peridot Intervertebral body fusion system is considered substantially equivalent to the primary predicate LnK Lumbar Interbody Fusion Cage System (K151140) and additional predicate Shurfit interbody device system (K092193). They are similar in design, material, scientific technologies and indications for use. And the Peridot Intervertebral body fusion system is considered substantially equivalent to the additional predicates SpaceVision OLIF (K153783) and MectaLIF Oblique (K110927) and ELSA Spacers (K161379) and Nuvasive Lumbar Interbody Implants (K151214, K161230). They are similar in design, material, scientific technologies and indications for use.

7. Performance Testing

The Peridot Intervertebral body fusion system conform to class II special controls guidance document: Intervertevbral body fusion device – Document issued on : June 12, 2007.

Mechanical testing includes static compression, static compression – shear, fatigue compression, fatigue compression – shear performed according to ASTM F2077-14, subsidence testing performed according to ASTM F2267-04 and , expulsion testing performed according to Draft ASTM F-04.25.02.02.

Results demonstrate comparable mechanical properties to the predicate device. No clinical date has been presented.

8. Conclusion

The Peridot Intervertebral body fusion system is substantially equivalent to legally marketed predicates.