February 4, 2021

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

Re: K202872
Trade/Device Name: Prase PEEK Anterior Cervical Interbody Spacer
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP
Dated: December 4, 2020
Received: December 11, 2020

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202872

Device Name
Prase PEEK Anterior Cervical Interbody Spacer

Indications for Use *(Describe)*
Prase PEEK Anterior Cervical Interbody Spacer is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. Prase PEEK Anterior Cervical Interbody Spacer is used to facilitate intervertebral body fusion in the cervical spine from the C3 to C7 disc levels using autograft bone. Prase PEEK Anterior Cervical Interbody Spacer is to be used with supplemental fixation. Patients should have at least six (6) weeks 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 September, 25, 2020

Trade Name	Prase PEEK Anterior Cervical Interbody Spacer
Regulatory Class	Class II
Regulation Name/Common Name	Intervertebral fusion device with bone graft, Cervical
Classification Name	Intervertebral body fusion device (21 CFR 888.3080)
Panel	Orthopedic
Product Code	ODP

2. Purpose of 510(k)

The GBS Commonwealth Co. Ltd., submits this submission for Initial product Introduction of Prase PEEK Anterior Cervical Interbody Spacer

3. Predicate or legally marketed devices which are substantially equivalent

1) Primary Predicate Device : K151677 LnK Cervical Interbody Fusion Cage System
2) Additional Predicate Device : K192026 Peridot Interverbral body fusion system
K200592 The GS Medical Anyplus PEEK Cage system

4. Description of the Device

The Prase PEEK Anterior Cervical Interbody Spacer is intervertebral body

fixation devices intended for use as an aid in spinal fusion. The Prase PEEK Anterior Cervical Interbody Spacer 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 instruments. The specific instruments are supplied dedicated tray and non-sterile. The device must be used in combination with the dedicated instruments supplied.

5. Indication for Use

Prase PEEK Anterior Cervical Interbody Spacer is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. Prase PEEK Anterior Cervical Interbody Spacer is used to facilitate intervertebral body fusion in the cervical spine from the C3 to C7 disc levels using autograft bone. Prase PEEK Anterior Cervical Interbody Spacer is to be used with supplemental fixation. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

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

Prase PEEK Anterior Cervical Interbody Spacer is considered substantially equivalent to the primary predicate LnK Cervical Interbody Fusion Cage System K151677and additional predicate device. They are similar in design, material, scientific technologies and indications for use.

7. Performance Testing

Mechanical testing includes static compression, static torsion, fatigue compression, fatigue torsion test were performed according to ASTM F2077-18, subsidence testing performed according to ASTM F2267-04.

8. Conclusion

Prase PEEK Anterior Cervical Interbody Spacer is substantially equivalent to legally marketed predicates.