October 4, 2018

GBS Commonwealth Co., Ltd.
Jimmy Kim
Regulatory Affairs
#1007-1, WOOLIM Lion's Valley B, 168, Gasan Digital 1-ro
Geumcheon-gu, Seoul
SOUTH KOREA

Re: K182059
Trade/Device Name: Prase MIS Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB
Dated: October 1, 2018
Received: October 3, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ronald P. Jean -S

for Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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)*
K182059

Device Name
Prase MIS Spinal System

Indications for Use *(Describe)*
The Prase MIS Spinal System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine. And the Prase MIS Spinal System can be used in an open approach and a percutaneous approach. The Prase MIS Spinal System is intended for the following indications:

• Degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies)
• Spondylolisthesis
• Trauma (i.e., fracture or dislocation)
• Spinal stenosis
• Curvatures (i.e., scoliosis, kyphosis, and for lordosis)
• Tumor
• Pseudarthrosis
• Failed previous fusion in skeletally mature patients.

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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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.
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Phone. 82-2-6925-4469
e-mail: Jimmy.kim@gbscommonwealth.com
Contact Person: Jimmy Kim
Date prepared October 4, 2018

Trade Name	Prase MIS Spinal System
Classification	21 CFR 888.3070 Thoracolumbosacral pedicle screw System, Class II Product Code: NKB

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

The GBS Commonwealth Co. Ltd., here by submits this traditional 510(k): for Initial product Introduction of Prase MIS Spinal System

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

1) Primary Predicate Device: K161766 Pathloc-L MIS Spinal System
2) Additional Predicate Device: K173645 JASPER Spinal Fixation System

4. **Description of the Device**

Prase MIS Spinal System consists of cannulated poly screws, straight rods, curved rods and set screw components that can be used via percutaneous surgical approach. The components are available in a variety of diameters and lengths in order to accommodate patient anatomy. All products are made of

titanium alloy (ASTM F136) and CoCrMo alloy (ASTM F1537) approved for medical use. The implants will be provided non-sterile.

5. **Indication for Use**

The Prase MIS Spinal System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine. And the Prase MIS Spinal System can be used in an open approach and a percutaneous approach. The Prase MIS Spinal System is intended for the following indications:

•Degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies)

•Spondylolisthesis

•Trauma (i.e., fracture or dislocation)

•Spinal stenosis

•Curvatures (i.e., scoliosis, kyphosis, and/or lordosis)

•Tumor

•Pseudoarthrosis

•Failed previous fusion

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

The Prase MIS Spinal System is considered substantially equivalent to legally marketed devices Pathloc-L MIS Spinal System. They are similar in design, material, scientific technologies and indications for use. The only different thing is shape of bone screw. We have evaluated equivalency of bone screw shape via mechanical test.

7. **Performance Testing**

The Static compression bending, tension, torsion, and fatigue test were performed according to ASTM F1717 on a worst-case, screw construct. The

mechanical test results demonstrated that the Pathloc-L MIS Spinal System performs as well as the predicate device.

8. Conclusion

The Prase MIS spinal system is substantially equivalent to legally marketed predicates.