June 19, 2019

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

Re: K190762
Trade/Device Name: The JASPER Spinal Fixation System II
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB
Dated: March 21, 2019
Received: March 25, 2019

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,

Ronald P. Jean, 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)*

K190762

Device Name
The JASPER Spinal Fixation System II

Indications for Use *(Describe)*

The JASPER Spinal Fixation System II is non-cervical spinal fixation devices intended for use as posterior pedicle screw fixation systems (T1-S2/ilium), or as an anterolateral fixation system (T8-L5). All components in the system are limited to skeletally mature patients. These devices are indicated as an adjunct to fusion for all of the following indications regardless of the intended use:

The JASPER Spinal Fixation System II is indicated for the following:
- Degenerative Disc Disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies)
- Spondylolisthesis
- Trauma (i.e., fracture or dislocation)
- Deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis)
- Tumor
- Stenosis
- Pseudoarthrosis
- Failed previous fusion

The JASPER Spinal Fixation System II is a pedicle screw system indicated for the treatment of severe spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.
In addition, the JASPER Spinal Fixation System II 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: degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudoarthrosis).

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.

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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South Korea
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E-mail: Jimmy.kim@gbscommonwealth.com

Contact Person: Jimmy Kim

Date prepared March, 14, 2019

Trade Name	The JASPER Spinal Fixation System II
Classification	21 CFR 888.3070 Thoracolumbosacral pedical 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 The JASPER Spinal Fixation System II.

The Purpose of this 510(k) submission is to combine the existing 510(k) clearance system (K173645 and K182059). The JASPER Spinal Fixation System II has the same intended use and fundamental scientific technology as the previously cleared system.

3. Predicate or legally marketed devices which are substantially equivalent

1) Primary Predicate Device: K173645 The JASPER Spinal Fixation System
2) Additional Predicate : K182059 The PRASE MIS Spinal System

4. Description of the Device

The JASPER Spinal Fixation System II is a top-loading multiple component, posterior(thraco-lumbar) spinal fixation system which consists of screws, hooks, rods, set screws, cross links, rod connectors and iliac connectors for spinal deformity system. The JASPER Spinal Fixation System II will allow surgeons to build a spinal implant construct to stabilize and promote spinal fusion.

All products are made of titanium alloy (Ti-6AI-4V ELI, ASTM F136) and CoCrMo alloy(Cobalt-28Chromium-6Molybdenum, ASTM F1537) approved for medical use.

5. Indication for Use

The JASPER Spinal Fixation System II is non-cervical spinal fixation devices intended for use as posterior pedicle screw fixation systems (T1-S2/ilium), or as an anterolateral fixation system (T8-L5). All components in the system are limited to skeletally mature patients. These devices are indicated as an adjunct to fusion for all of the following indications regardless of the intended use:

The JASPER Spinal Fixation System II is indicated for the following:

- Degenerative Disc Disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies)
- Spondylolisthesis
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- Stenosis
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6. **Comparison of the technological characteristics of the subject and predicate devices**

The JASPER Spinal Fixation System II is the same as the legally marketed devices JASPER Spinal Fixation System and PRASE MIS Spinal System. It has the same design, material, scientific technologies and indications for use.

7. Performance Testing

No new mechanical testing was performed as no non-previously cleared components were added to the JASPER Spinal Fixation System II.

8. SE Determination

The JASPER Spinal Fixation System II has been demonstrated to be same to the predicate system(s) with respect to technical characteristics, performance, and intended use. The information provided within this premarket notification supports substantial equivalence to the predicate device(s).