May 13, 2019

GS Medical Co., Ltd.
% Ms. Manjusha Bharadwaj
Senior Regulatory/Quality Consultant
RQMIS, Inc.
110 Haverhill Road
Amesbury, Massachusetts 01913

Re: K190170
Trade/Device Name: MVP Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: March 18, 2019
Received: March 20, 2019

Dear Ms. Bharadwaj:

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,

for CAPT Raquel Peat, PhD, MPH, USPHS
Director
Office of Health Technology 6
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)*
K190170

Device Name
MVP Cervical Plate System

Indications for Use *(Describe)*
The MVP Cervical Plate System is intended for anterior cervical fixation (C2-C7) in skeletally mature patients as an adjunct to fusion for the following indications:

- Degenerative disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies)
- Spondylolisthesis
- Trauma (including fracture or dislocation)
- Spinal Stenosis
- Deformities or curvatures (kyphosis, lordosis, or scoliosis)
- Tumors
- Pseudoarthrosis
- Failed Previous Fusion

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

GS Medical MVP Cervical Plate System

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

GS Medical Co., Ltd.
90, Osongsaengmyeong 4-Ro
Osong-Eup, Cheongwon-Gun, KR 363-951
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Date Prepared: January 11, 2019

Name of Device and Name/Address of Sponsor

Trade Name: MVP Cervical Plate System
GS Medical Co., Ltd.
90, Osongsaengmyeong 4-Ro
Osong-Eup, Cheongwon-Gun, KR 363-951

Common or Usual Name

Device Type: Anterior Cervical Plating System

Classification Name: 21 CFR 888:3060 Spinal Intervertebral Body Fixation Orthosis

Orthopedics, Product Code KWQ

Reason for 510(k) Submission

GS Medical is submitting this traditional 510(k) to gain clearance for the MVP Cervical Plate System. This device includes plates and screws of various sizes, as well as associated instruments. GS Medical believes that the MVP Cervical Plate System is substantially equivalent to the following:

- Synthes Anterior CSLP System (K030866) – primary
- NUVASIVE HELIX MINI ACP SYSTEM (K073275) -- additional
- Depuy UNIPLATE 2 Anterior Cervical Plate System (K100070) - additional

Intended Use / Indications for Use

The MVP Cervical Plate System is intended for anterior cervical fixation (C2-C7) in skeletally mature patients as an adjunct to fusion for the following indications:

- Degenerative disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies)
- Spondylolisthesis
- Trauma (including fracture or dislocation)
- Spinal stenosis
- Deformities or curvatures (kyphosis, lordosis, or scoliosis)
- Tumors
- Pseudoarthrosis
- Failed previous fusion

Technological Characteristics

The MVP Cervical Plate System is a multiple component system that comprises several sizes of plates and screws and associated manual surgical instruments. The MVP Cervical Plate System implants are supplied non-sterile, are single use, and are fabricated from medical grade titanium alloy (Ti6Al4V ELI, ASTM F 136). The Instruments in the MVP Cervical Plate System are supplied non-sterile, are reusable, and are fabricated from titanium alloy Ti-6Al-4V or stainless steel.

Performance Data

Testing and analyses performed indicate that the MVP Cervical Plate System is as mechanically sound as the predicate device. Testing included static compression, dynamic compression, and torsional testing per ASTM F1717-15, as well as reprocessing instruction validation. The results demonstrate that the acceptance criteria defined by predicate device performance were met.

Substantial Equivalence

The intended use and technological characteristics (e.g., design, materials, principle of operations) of the MVP Cervical Plate System is substantially equivalent to the primary predicate Synthes Anterior CSLP System (K030866). Performance data demonstrates that the MVP Cervical Plate System is substantially equivalent to the Synthes Anterior CSLP System (K030866).