October 23, 2017

GS Medical Co., Ltd.
% Mr. Barry E. Sands
President and Founder
RQMIS, Inc.
110 Haverhill Road, Suite 526
Amesbury, Massachusetts 01913

Re: K172546
Trade/Device Name: AnyPlus® Spinal Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB, KWP, KWQ
Dated: August 22, 2017
Received: August 23, 2017

Dear Mr. Sands:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

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)*
K172546

Device Name
AnyPlus® Spinal Fixation System

Indications for Use *(Describe)*
The AnyPlus Spinal Fixation System are non-cervical spinal fixation devices intended for use as posterior pedicle screw fixation systems (T1 – S2), a posterior hook fixation system (T1 – L5),or as an anterolateral fixation system (T8 – L5). All components are limited to skeletally mature patients. System components are to be used for immobilization and stabilization of the spine as an adjunct to fusion. These devices are indicated for all of the following indications regardless of the intended use: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis, Scheuermann's Disease), tumor, stenosis, pseudoarthrosis, and 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.

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510(k) SUMMARY

GS Medical's AnyPlus Spinal Fixation System

Submitter: GS Medical Co., Ltd.
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Geumcheon-gu, Seoul, Korea
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Contact Person: Barry Sands
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Amesbury, MA 01913
Phone: 978-358-7307

Date Prepared: August 10, 2017

Name of Device: AnyPlus® Spinal Fixation System

Common or Usual Name: Pedicle screw system

Classification Name: 888.3070 – Thoracolumbosacral Pedicle Screw System
888.3050 – Spinal Interlaminal Fixation Orthosis
888.3060 – Spinal Intervertebral Body Fixation Orthosis

Product Codes: NKB
KWP
KWQ

Predicate Device: *Primary:* AnyPlus® Spinal Fixation System (K091717)
Secondary: GSS Pedicle Screw System (K053573)

Intended Use/ Indications for Use: The AnyPlus Spinal Fixation System are non-cervical spinal fixation devices intended for use as posterior pedicle screw fixation systems (T1 – S2), a posterior hook fixation system (T1 – L5), or as an anterolateral fixation system (T8 – L5). All components are limited to skeletally mature patients. System components are to be used for immobilization and stabilization of the spine as an adjunct to fusion. These devices are indicated for all of the following indications regardless of the intended use: degenerative disc

disease (defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis, Scheuermann's Disease), tumor, stenosis, pseudoarthrosis, and failed previous fusion.

Description: AnyPlus Spinal Fixation System is made of devices for fixation of the noncervical spine. They include smooth rods, plates, screws, hooks, nut, screws, and transverse links. The purpose of this submission was to add components to the Anyplus Spinal Fixation System.

Performance Data: Constructs with the subject components were tested using the following ASTM F1717 tests: static compression bending, static torsion, and dynamic compression bending.

Substantial Equivalence: The AnyPlus Spinal Fixation System is as safe and effective as the predicates Any Plus Spinal Fixation System (K091717) and GSS Pedicle Screw System (K053573). The AnyPlus Spinal Fixation System has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate devices. The mechanical testing demonstrates substantially equivalent mechanical performance to that of the predicates. Thus, the AnyPlus Fixation System is substantially equivalent.