GS Medical Co. Ltd.
% Barry Sands
President and Founder
RQMIS, Inc
110 Haverhill Rd
Suite 524
Amesbury, Massachusetts 01913

April 3, 2024

Re: K240350
Trade/Device Name: AnyPlus II 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: February 1, 2024
Received: February 5, 2024

Dear Barry 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Eileen Cadel -S
Digitally signed by Eileen Cadel -S
Date: 2024.04.03 10:12:50 -04'00'

for

Colin O'Neill, MBE
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K240350

Device Name
AnyPlus II Spinal Fixation System

Indications for Use *(Describe)*
The GS Medical AnyPlus II Spinal Fixation System is composed of a non-cervical spinal fixation devices. It is intended for use as posterior pedicle screw fixation system (T1-S2), a posterior hook fixation system (T1-L5), or as an anterolateral fixation system (T8-L5). All components in the system 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 following indications regardless of intended use: 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, 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

I. 510(K) SUMMARY

GS Medical's AnyPlus II Spinal Fixation System

A. SUBMITTER'S ADDRESS, TELEPHONE NUMBER, CONTACT PERSON

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Date Prepared: January 30, 2024

B. SUBJECT DEVICE

Trade/Proprietary Name of Device:	Anyplus II Spinal Fixation System
Common Or Usual Name:	Pedicle Screw System
Classification Name:	Thoracolumbosacral Pedicle Screw System
Regulation Number:	21 CFR 888.3070
Classification:	Class 2
Product Code:	NKB, KWP, KWQ

C. PREDICATE DEVICES

Primary Predicate:

Trade/Proprietary Name of Device:	Anyplus Spinal Fixation System
510(k) number	K172546
Common Or Usual Name:	Pedicle Screw System
Classification Name:	Thoracolumbosacral Pedicle Screw System
Regulation Number:	21 CFR 888.3070
Classification:	Class 2
Product Code:	NKB, KWP, KWQ, MNH, MNI

D. INDICATIONS FOR USE

The GS Medical AnyPlus II Spinal Fixation System is composed of a non-cervical spinal fixation devices. It is intended for use as posterior pedicle screw fixation system (T1-S2), a posterior hook fixation system (T1-L5), or as an anterolateral fixation system (T8-L5). All components in the system 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 following indications regardless of intended use: 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, Scheuermann's Disease), tumor, stenosis, pseudoarthrosis, and failed previous fusion.

E. DEVICE DESCRIPTION

The AnyPlus II Spinal Fixation System consists of various screws (mono and polyaxial screws, reduction screw, canulated screws, long arm screws, cortical screws, and a set screw). The screws are available with diameters ranging from 4.5 to 10.5mm, and lengths ranging from 20-100mm in 5mm increments. They are available in non-cannulated, cannulated, and longarm geometries with both mono and poly types for each geometry option. All AnyPlus II Spinal Fixation System implant components are manufactured from Ti6AI4V ELI according to ASTM F136.

These implants are supplied non-sterile and are not reusable. The instruments in this system are supplied non-sterile, are reusable, and patient contacting materials are fabricated from Precipitation Hardened Stainless Steels (STS630 and STS555) that complies with ASTM F899.

F. PERFORMANCE DATA

The worst-case construct of the AnyPlus II Spinal Fixation System underwent testing according to ASTM F1717, specifically: static and dynamic axial compression bending testing and static torsion testing. The results demonstrate that the subject device is substantially equivalent to the primary predicate's (K091717) biomechanical performance.

G. CONCLUSION

The technological differences between the subject device and the predicates (K172546) do not raise new questions of safety and effectiveness. Any differences in technological characteristics have been tested and documented. The subject device and predicate(s) (K172546) have been determined to be substantially equivalent in terms of indications for use, materials, performance, sterility, and biocompatibility.