August 10, 2020

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

Re: K200592
Trade/Device Name: The GS Medical AnyPlus® PEEK Cage System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP
Dated: July 10, 2020
Received: July 15, 2020

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. 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,

Brent Showalter, Ph.D.
Acting 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)*

K200592

Device Name
GS Medical AnyPlus® PEEK Cage System

Indications for Use *(Describe)*

The GS Medical AnyPlus® PEEK Cage System is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. GS Medical AnyPlus® PEEK Cage System are used to facilitate intervertebral body fusion in the cervical spine at the C3 to C7 disc levels using autograft bone. GS Medical AnyPlus® PEEK Cage System are to be used with supplemental fixation. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

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 Co., Ltd.

AnyPlus® PEEK Cage System

Manufacturer:	GS Medical Co., Ltd. 90, Osongsaengmyeong 4-ro Osong-eup Cheongwon-gun Chungcheongbuk-do 363-951 Korea
Date:	March 2, 2020
Submitted by:	GS Medical Co., Ltd
Company Contact	Andrea Watt +1 949-380-6385 awatt@gsmedical.com
US Agent Information Official Correspondent	RQMIS Inc. Mr. Barry E. Sands 110 Haverhill Rd, Suite 526 Amesbury, MA 01913 Ph: 978-358-7307 barrysands@rqmis.com
Proprietary Name:	The GS Medical AnyPlus® PEEK Cage System
Performance standards:	The GS Medical AnyPlus® PEEK Cage System was non-clinically tested according to the ASTM 2077-11 and ASTM F2267-04 performance standards.
Regulation:	21 CFR 888.3080
Common/Usual Name:	Cervical Spinal Fusion Device, IBF Device
Classification name:	Intervertebral body fusion device – Cervical
Review Panel:	Orthopedic
Product Code:	ODP
Device Class:	Class II
Substantial Equivalence:	Substantial equivalence for the GS Medical AnyPlus® PEEK Cage System is based on its similarities in indications for use, design features, operational principles and material composition when compared to the predicate devices.

Primary Predicate Device:	K153517 GS Medical AnyPlus® Cervical PEEK Cage The subject device is substantially equivalent to similar previously cleared devices.
Device Description:	The GS Medical AnyPlus® PEEK Cage System device is designed for restoring the height of the intervertebral space after resection of the disc. AnyPlus® PEEK Cage System device consists of implants available in various heights and lordotic configurations with an open architecture to accept packing of bone graft material. The intervertebral body fusion devices are made of poly-ether-ether- ketone (PEEK Optima LT1) body with the X-ray (radio-opaque) markers made of Tantalum. The AnyPlus® PEEK Cage System devices are radiolucent allowing X-ray visualization to verify device placement. AnyPlus® PEEK Cage System device is supplied sterile and non-sterile and is intended for single use only. AnyPlus® PEEK Cage System is designed for interbody stabilization of the cervical spine.
Intended Use:	The GS Medical AnyPlus® PEEK Cage System is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. GS Medical The GS Medical AnyPlus® PEEK Cage System is used to facilitate intervertebral body fusion in the cervical spine at the C3 to C7 disc levels using autograft bone. GS Medical The GS Medical AnyPlus® PEEK Cage System is to be used with supplemental fixation. Patients should have at least six (6) weeks of non- operative treatment prior to treatment with an intervertebral cage.
Summary of Technological Characteristics	The GS Medical AnyPlus® PEEK Cage System devices are designed for restoring the height of the intervertebral space after resection of the disc. The GS Medical AnyPlus® PEEK Cage System device consist of implants available in various heights and lordotic configurations with an open architecture to accept packing of bone graft material. The implants are made of polyether-ether- ketone (PEEK) body with the x-ray markers made of Tantulum. The intended use, technological characteristics, mode of action and materials of construction are the same as those of the referenced predicate devices.

Device Materials

Material	Standard
Polyether-ether-ketone (PEEK)	ASTM F2026:17
Unalloyed Tantalum	ASTM F560-17
Wrought Stainless Steel	ASTM F899-19

Non-Clinical Testing

The GS Medical AnyPlus® PEEK Cage System devices were tested according to the ASTM 2077, specifically, Static and Dynamic Axial Compression, Static and Dynamic Compression-Shear Testing, Static and Dynamic Torsion Testing Expulsion Testing and Static Subsidence testing under Axial Compression, per ASTM 2267. All performance test results were equivalent to or higher than a legally marketed predicate device. Pyrogen limit specifications were tested and met on "worst-case" model, complying with FDA guidance an specifications.

Clinical Testing

No clinical testing was performed.

Conclusion

The GS Medical AnyPlus® PEEK Cage System has the same intended use and similar indications, principles of operation, and technological characteristics as the predicate device. The minor differences in the designs do not raise any new questions of safety or effectiveness. Performance data demonstrates that the AnyPlus® Cervical PEEK Cage System are as safe and effective as the predicate device. Thus, the AnyPlus® Cervical PEEK Cage System is substantially equivalent to the predicate device.