July 27, 2022

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

Re: K221687
Trade/Device Name: Pegasus-X Expandable PLIF System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: June 8, 2022
Received: June 10, 2022

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 (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,

for
Brent Showalter, 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221687

Device Name
Pegasus-X Expandable PLIF System

Indications for Use *(Describe)*
GS Medical's Pegasus-X Expandable PLIF System is indicated for use with autogenous bone graft in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous spinal levels from L2-S1. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. These patients should have had six months of non-operative treatment. These DDD patients may have up to Grade 1 spondylolisthesis at the involved level(s). The Pegasus-X Expandable PLIF Cage is to be combined with internal supplemental fixation cleared for use in the lumbar spine.

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 Pegasus-X Expandable PLIF System

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

Sam Camp
Senior Engineer
GS Medical Co. Ltd.
90 Osongsaengmyong 4-ro
Osong-eup, Heungdeok-gu, Gheongju-si,
Chungcheongbuk-do 28161 Korea
Tel.: 405-535-2719
Email: scamp@gsmedicalusa.com

Contact Person:

Barry E. Sands
RQMIS Inc.
110 Haverhill Road, Suite 524
Amesbury, MA 01913
Phone: (978) 358-7307
Email: barrysands@rqmis.com
Facsimile: (978) 477-0206

Date Prepared: June 3, 2022

II. SUBJECT DEVICE

Trade/proprietary name of device:	Pegasus-X Expandable PLIF Cage
Common or Usual Name:	Intervertebral Body Fusion Device
Classification Name:	Intervertebral Body Fusion Device with Bone Graft, Lumbar
Regulation Number:	21 CFR 888.3080
Classification:	Class II
Product Code(s)	MAX

III. PREDICATE DEVICES

Primary Predicate

Name	Globus Rise Spacer
510(k) number	K113447
Product Code	MAX
CFR	21 C.F.R. 888.3080
Classification	Class II

Additional Predicate

Name	AnyPlus PEEK PLIF
510(k) number	K100516
Product Code	MAX
CFR	21 C.F.R. 888.3080
Classification	Class II

IV. DEVICE DESCRIPTION

The Pegasus-X Expandable PLIF Cage devices are designed for restoring the height of the intervertebral space after resection of the disc. The Pegasus-X Expandable PLIF Cage devices consist of implants in various heights, footprints, and lordotic configurations with architecture designed to accept pre and post packing of bone graft material. The intervertebral body devices are made of titanium alloy (Ti-6AL-4V ELI). The Pegasus-X Expandable PLIF Cage devices are not radio lucent but have large windows through the sides that will allow visualization of the placement and subsequent bone fusion. The Expandable PLIF Cage (Posterior Lumbar Interbody Fusion Cage) are designed for segments L2 to S1.

V. INTENDED USE/INDICATIONS FOR USE

GS Medical's Pegasus-X Expandable PLIF Cage is indicated for use with autogenous bone graft in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous spinal levels from L2-S1. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. These patients should have had six months of non-operative treatment. These DDD patients may have up to Grade 1 spondylolisthesis at the involved level(s). The Pegasus-X Expandable PLIF Cage is to be combined with internal supplemental fixation cleared for use in the lumbar spine.

The intented use of the subject device and the predicates are identical.

VI. TECHNOLOGICAL CHARACTERISTICS

The subject device cages are provided in rectangular shape and have space to hold bone graft material. Upon implantation, the device can be expanded to any height within the allowed range as specified for each device description (cage combination). The expansion of the cage is achieved via the Torque Limiting Handle. The components are manufactured from Titanium Alloy (Ti-6Al-4V ELI) meeting the specifications of ASTM F136 Standard.

The Subject cage implants are available in various heights, footprints, and lordotic angles to suit the individual patient's pathology and anatomical conditions. The primary and additional predicates have rectagular shape, with various footprints, height and lordotic angles. Both the subject device, primary and additional predicate are rectangular in shape, have lordotic angles, and are available in various heights and widths. The shape, width, lordosis are withing the maximum primary predicate and additional predicate range. The highet expansion of the subject cage is within the range of the primary predicate highet expansion range. Since there is no significant difference in technological characteristcs between the subject and predicate devices, we conclude that the subject device is substantially equivalent to Primary and additional predicate.

VII. PERFORMANCE DATA

The worst-case cage of the Pegasus-X Expandable PLIF Cage system underwent testing according to ASTM 2077, specifically static and dynamic axial compression testing, shear static and dynamic compression, expulsion testing, and subsidence testing according to ASTM F2267. The results met all acceptance criteria, and the subject device cage is equivalent to additional predicate biomechanical performance.

VIII. CONCLUSION

The Pegasus-X Expandable PLIF Cage has been found to be substantially equivalent to the primary predicate with respect to technical characteristics, design, materials, and intended use. And to the additional predicate with respect to performance. The technological differences between the subject device and the predicate do not raise new questions of safety and effectiveness.