April 26, 2023

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

Re: K223868
Trade/Device Name: PYXIS 3D Titanium Cage System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: February 28, 2023
Received: March 1, 2023

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 -S

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)*
K223868

Device Name
PYXIS 3D Titanium Cage System

Indications for Use *(Describe)*
The PYXIS 3D Titanium Cage System is indicated for use with autogenous bone graft in skeletally mature patients with degenerative disc disease ("DDD") at one or two contiguous spinal levels from L2-S 1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by 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 or retrolisthesis at the involved level(s).

The PYXIS 3D Titanium Cage System is to be combined with 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.

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

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510(k) SUMMARY

GS Medical Co. Ltd.

PYXIS 3D Titanium Cage System

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

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Phone: 978-358-7307
Email: regulatorysubmissions@rqmis.com

Date Prepared: April 25, 2023

II. SUBJECT DEVICE

Trade/proprietary name of device:	PYXIS 3D Titanium Cage System
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:

- EIT Cellular Titanium Cervical Cages, EIT Cellular Titanium PLIF Cages, EIT Cellular Titanium TLIF Cages, EIT Cellular Titanium ALIF Cages
  K172888
  MAX, ODP
  21 CFR 888.3080
  Class II

Additional Predicates:

- EIT Cellular Titanium Lumbar cage LLIF
  K181644
  MAX
  21 CFR 888.3080
  Class II

- AnyPlus PEEK Cage
  K100516
  MAX
  21 CFR 888.3080
  Class II

IV. INTENDED USE/INDICATIONS FOR USE:

The PYXIS 3D Titanium Cage System is indicated for use with autogenous bone graft in skeletally mature patients with degenerative disc disease ("DDD") at one or two contiguous spinal levels from L2-S 1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by 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 or retrolisthesis at the involved level(s).

The PYXIS 3D Titanium Cage System is to be combined with supplemental fixation cleared for use in the lumbar spine.

V. DEVICE DESCRIPTION/TECHNOLOGICAL CHARACTERISTICS

The GS Medical PYXIS 3D Titanium Cage System devices are designed for restoring the height of the intervertebral space after resection of he disc. They system consists of various cages for intervertebral body fusion ranging in height from 5mm-21mm with multiple lordotic options depending on the approach.

The components are manufactured from 3D printed Titanium Alloy (Ti-6Al-4V ELI) meeting the specifications of ASTM F3001 Standard Specification for Additive Manufacturing Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) with Powder Bed Fusion.

The PYXIS 3D Titanium Cage System implants are available in various heights, footprints, and lordotic angles to suit the individual patient's pathology and anatomical conditions.

VI. PERFORMANCE DATA

The worst-case cage of the PYXIS 3D Titanium 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.

VII. CONCLUSION

The PYXIS 3D Titanium 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 minor technological differences between the subject device and the predicate do not raise new questions of safety and effectiveness.