August 20, 2024

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

Re: K241738
Trade/Device Name: PYXIS 3D Titanium Cervical Cage System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP
Dated: June 11, 2024
Received: June 17, 2024

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 (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,

Katherine D. Kavlock -S

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241738

Device Name

PYXIS 3D Titanium Cervical Cage system

Indications for Use *(Describe)*

The GS Medical PYXIS 3D Titanium Cervical Cages 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 PYXIS 3D Titanium Cervical Cages are used to facilitate intervertebral body fusion in the cervical spine at the C3 to C7 disc levels using autograft bone. GS Medical PYXIS 3D Titanium Cervical Cages 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.

PYXIS 3D Titanium Cervical Cage System

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

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Date Prepared: June 10, 2024

II. SUBJECT DEVICE

Trade/proprietary name of device:	PYXIS 3D Titanium Cervical Cage System
Common or Usual Name:	Intervertebral Body Fusion Device
Classification Name:	Intervertebral Body Fusion Device with Bone Graft, Cervical
Regulation Number:	21 CFR 888.3080
Classification:	Class II
Product Code:	ODP

III. PREDICATE DEVICES

Primary Predicate:

- EIT Cellular Titanium® Cervical Cage
  K172888
  ODP
  21 CFR 888.3080
  Class II

Additional Predicate:

- AnyPlus Cervical PEEK Cage
  K153517
  ODP
  21 CFR 888.3080
  Class II

- PYXIS 3D Titanium cage System
  K223868
  MAX
  21 CFR 888.3080
  Class II

IV. INTENDED USE/INDICATIONS FOR USE

The GS Medical PYXIS 3D Titanium Cervical Cages 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 PYXIS 3D Titanium Cervical Cages are used to facilitate intervertebral body fusion in the cervical spine at the C3 to C7 disc levels using autograft bone. GS Medical PYXIS 3D Titanium Cervical Cages 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.

V. DEVICE DESCRIPTION/TECHNOLOGICAL CHARACTERISTICS

The GS Medical PYXIS 3D Titanium Cervical Cage System devices are designed for restoring the height of the intervertebral space after resection of the disc.

The intervertebral body fusion devices are made of 3D printed titanium alloy (Ti-6Al-4V) in accordance with and manufactured as per ASTM F3001. The material and manufacturing process of the subject device, PYXIS 3D Titanium Cervical Cage is identical to the additional predicate (PYXIS 3D Titanium Cage System, K223868).

The PYXIS 3D Titanium Cervical Cage System implants are available in various heights, footprints, and lordotic angles to suit the individual patient's pathology and anatomical conditions. The subject device cages ranging in height from 5mm-10mm in 1 mm increments with 0°, 4°, and 8° options. Also in 4.5mm hight for the 0° angle. The cages are provided in three distinct footprints.

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, static and dynamic compression shear testing, static and dynamic Torsion testing; expulsion testing, and subsidence testing according to ASTM F2267.

VII. CONCLUSION

The technological differences between the subject device and the predicates (K172888 and K153517) do not raise new questions of safety and effectiveness. Any differences in technological characteristics have been tested and documented. The subject device and predicates (K172888 and K153517) have been determined to be equivalent in terms of indications for use, materials, performance, sterility, and biocompatibility.