February 9, 2023

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

Re: K222041
Trade/Device Name: CYGNUS-C Standalone ACIF System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVE
Dated: January 11, 2023
Received: January 11, 2023

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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222041

Device Name
CYGNUS-C Standalone ACIF system

Indications for Use *(Describe)*
The GS Medical CYGNUS-C Standalone ACIF 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. The GS Medical CYGNUS-C Standalone ACIF System is used to facilitate intervertebral body fusion in the cervical spine at the C3 to C7 disc levels using autograft bone. The GS Medical CYGNUS-C Standalone ACIF System is to be used with two titanium alloy screws which accompany the implant and does not require 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.

510(k) SUMMARY

GS Medical's CYGNUS-C Standalone ACIF system

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

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Date Prepared: February 3, 2023

II. SUBJECT DEVICE

Trade/proprietary name of device:	CYGNUS-C Standalone ACIF system
Common or Usual Name:	Intervertebral Body Fusion Device
Classification Name:	Intervertebral fusion device with integrated fixation, cervical
Regulation Number:	21 CFR 888.3080
Classification:	Class II
Product Code(s)	OVE

III. PREDICATE DEVICES

Primary Predicate

Name	Coalition Spacer
510(k) number	K131449
Product Code	OVE
CFR	21 C.F.R. 888.3080
Classification	Class II

First Additional Predicate

Name	AnyPlus Cervical PEEK Cage
510(k) number	K153517
Product Code	ODP
CFR	21 C.F.R. 888.3080
Classification	Class II

Second Additional Predicate

Name	CxHA PEEK Cervical IBF
510(k) number	K181115
Product Code	ODP
CFR	21 C.F.R. 888.3080
Classification	Class II

IV. DEVICE DESCRIPTION

Intended Use/Indications for Use:

The GS Medical CYGNUS-C Standalone ACIF 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. The GS Medical CYGNUS-C Standalone ACIF System is used to facilitate intervertebral body fusion in the cervical spine at the C3 to C7 disc levels using autograft bone. The GS Medical CYGNUS-C Standalone ACIF System is to be used with two titanium alloy screws which accompany the implant and does not require supplemental fixation. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

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

V. TECHNOLOGICAL CHARACTERISTICS

The CYGNUS-C Standalone ACIF System cages are designed for restoring the height of the intervertebral space after resection of the disc while also providing biomechanical

stability with the addition on an integrated plate. This integrated plate allows for the user to bypass using an additional plate as seen with traditional ACIF spacers. The CYGNUS-C Standalone ACIF System devices consist of implants available in various heights and lordotic configurations with an open architecture to accept packing of bone graft material. The Subject device also contains supplementary fixation screw. The intervertebral body fusion devices are made of hydroxyapatite polyether-ether-ketone (HA PEEK OPTIMA LT1) body with a titanium alloy (Ti-6Al-4V) plate and X-ray (radio-opaque) markers made of tantalum. The supplementary screws are made up of titanium alloy (Ti-6Al-4V).

VI. PERFORMANCE DATA

The worst-case cage construct of the CYGNUS-C ACIF Standalone System underwent testing according to ASTM 2077, specifically static and dynamic axial compression testing; shear static and dynamic compression; static and dynamic torsion testing; 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. BIOCOMPATIBILITY

The biocompatibility of the subject implant body is based on the FDA's clearance of first additional predicate that contains bone contact materials made up of identical material (HA PEEK OPTIMA LT1) and same use as of subject device. And the biocompatibility of the plate and screw is based on the FDA's clearance of primary predicate that contains bone contact materials made up of identical material (Ti-6Al-4V) and same use as of subject device. The biocompatibility of the surgical instruments is based on the FDA's clearance of the first additional predicate that contains instruments made up of identical material and same use as of subject device.

VIII. CONCLUSION

The CYGNUS-C Standalone ACIF System has been found to be substantially equivalent to the primary predicate with respect to technical characteristics, design, materials, and intended use. And to the first 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.