July 20, 2023

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

Re: K231808
Trade/Device Name: QUASAR Standalone ACIF System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVE
Dated: June 19, 2023
Received: June 20, 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,

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)*
K231808

Device Name
QUASAR Standalone ACIF System

Indications for Use *(Describe)*
The GS Medical QUASAR Stand-alone 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 QUASAR Stand-alone ACIF System is used to facilitate intervertebral body fusion in the cervical spine at the C3 to C7 disc levels using autograft bone. When the GS Medical QUASAR Standalone ACIF System is used with all the titanium alloy screws for which the implant is designed it does not require supplemental fixation. When used with fewer screws the implant should be used in conjunction with supplemental fixation that has been cleared for use in the cervical spine. 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's QUASAR Standalone ACIF System

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Date Prepared: June 19, 2023

B. SUBJECT DEVICE

Trade/proprietary name of device:	QUASAR Standalone ACIF System
Common or Usual Name:	Intervertebral body fusion device
Classification Name:	Intervertebral body fusion device
Regulation Number:	888.3080
Classification:	Class II
Product Code:	OVE - Intervertebral Fusion Device With Integrated Fixation, Cervical

C. PREDICATE DEVICES

Primary Predicate
CYGNUS-C Standalone ACIF System (K222041)
888.3080 - Intervertebral body fusion device
OVE (Class 2) - Intervertebral Fusion Device With Integrated Fixation, Cervical

D. INDICATIONS FOR USE

The GS Medical QUASAR 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 QUASAR Standalone ACIF System is used to facilitate intervertebral body fusion in the cervical spine at the C3 to C7 disc levels using autograft bone. When the GS Medical QUASAR Standalone ACIF System is used with all the titanium alloy screws for which the implant is designed it does not require supplemental fixation. When used with fewer screws the implant should be used in conjunction with supplemental fixation that has been cleared for use in the cervical spine. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

E. DEVICE DESCRIPTION

The subject device, the QUASAR 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 QUASAR 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 supplementary fixation screws are used along with the subject device cage and plate.

The intervertebral body fusion devices are made of hydroxyapatite polyether-ether-ketone (HA PEEK OPTIMA LT1) body with Titanium alloy plates (Ti-6Al-4V) and supplementary screws made up of Titanium alloy (Ti-6Al-4V).

F. PERFORMANCE DATA

The worst-case cage construct of the QUASAR Standalone ACIF 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 the primary predicate biomechanical performance.

G. STERILITY

The subject device, QUASAR Standalone ACIF System's cage implants are provided in both non-sterile (end-user sterilized) and sterile versions.

H. CONCLUSION

The technological differences between the subject device and the predicate (K222041) do not raise new questions of safety and effectiveness. Any differences in technological characteristics have been tested and documented. The subject device and predicate(s) (K222041) have been determined to be equivalent in terms of indications for use, materials, performance, sterility, and biocompatibility.