March 23, 2023

G21, S.r.l.
℅ Barry E. Sands
President and Founder
RQMIS, Inc.
110 Haverhill Rd.
Amesbury, Massachusetts 01913

Re: K223441
Trade/Device Name: SpaceFlex Acetabular Cup
Regulation Number: 21 CFR 888.3390
Regulation Name: Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis
Regulatory Class: Class II
Product Code: KWY, KWL
Dated: February 24, 2023
Received: February 24, 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,

Sara S. Thompson -S

For

Laurence D. Coyne, Ph.D.
Director
DHT6C: Division of Restorative, Repair
And Trauma 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)*
K223441

Device Name
SpaceFlex Acetabular Cup

Indications for Use *(Describe)*
The SpaceFlex Acetabular Cup consists of disposable cement spacer molds indicated for use to mold a temporary Acetabular cup replacement for skeletally mature patients undergoing a two-stage procedure due to a septic process.

The temporary prosthesis is molded using low viscosity antibiotic polymethylmethacrylate bone cement (G3A 40 bone cement) and positioned into the acetabular cavity following removal of the existing acetabular and femoral components and radical debridement.

The molded acetabular cup is intended for use in conjunction with systemic antimicrobial antibiotic therapy (standard treatment approach to an infection). The molded temporary Acetabular cup prosthesis is indicated for an implantation period of 180 days or less. Because of inherent mechanical limitations of the device material (Bone Cement), the molded temporary prosthesis is only indicated for patients who will consistently use traditional mobility assist devices (e.g., crutches, walkers) throughout the implant period.

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

G21's SpaceFlex Acetabular Cup

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

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Date Prepared: March 23, 2023

II. SUBJECT DEVICE

Trade/proprietary name of device:	SpaceFlex Acetabular Cup
Common or Usual Name:	Acetabular Cup Mold
Classification Name:	Prosthesis, Hip, Hemi-, Femoral, Metal/Polymer, Cemented or Uncemented
Regulation Number:	21 CFR 888.3390 (Prosthesis, Hip, Hemi-, Femoral, Metal/Polymer, Cemented or Uncemented) 21 CFR 888.3360 (Hip Joint femoral (hemi-hip) metallic cemented or uncemented prosthesis
Classification: Class II	Class II
Product Code(s)	KWY, KWL

III. PREDICATE DEVICES

Primary Predicate:

Product Name:	REMEDY Acetabular Cup
510(k) Number:	K191981
Product Code:	KWL, KWY, KWZ
C.F.R.:	21 CFR 888.3360
Classification:	Class II

Reference Device:

Product Name:	SpaceFlex Hip
510(k) Number:	K192041
Product Code:	MBB, KWL, KWY
C.F.R.:	21.CFR.888.3027
Classification:	Class II

Reference Device:

Product Name:	SpaceFlex Knee
510(k) Number:	K190216, K201960
Product Code:	MBB, JWH
C.F.R.:	21.CFR.888.3027
Classification:	Class II

IV. DEVICE DESCRIPTION

Intended Use/Indications for Use:

The SpaceFlex Acetabular Cup consists of disposable cement spacer molds indicated for use to mold a temporary Acetabular cup replacement for skeletally mature patients undergoing a two-stage procedure due to a septic process.

The temporary prosthesis is molded using low viscosity antibiotic polymethylmethacrylate bone cement (G3A 40 bone cement) and positioned into the acetabular cavity following removal of the existing acetabular and femoral components and radical debridement.

The molded acetabular cup is intended for use in conjunction with systemic antimicrobial antibiotic therapy (standard treatment approach to an infection). The molded temporary Acetabular cup prosthesis is indicated for an implantation period of 180 days or less. Because of inherent mechanical limitations of the device material (Bone Cement), the molded temporary prosthesis is only indicated for patients who will consistently use traditional mobility assist devices (e.g., crutches, walkers) throughout the implant period.

V. TECHNOLOGICAL CHARACTERISTICS

The combinations of the following elements provide the modularity of the temporary prosthesis:

- Lower mold. The lower mold, made of polypropylene material, has a fixed diameter and is coupled with one of three upper molds with four clips.
- Upper mold. The upper mold, made of polypropylene material, is provided in three diameters. The mold consists of five channels for air flow during the injection process and has four holes in which the clips are placed to couple it with the selected lower mold.
- Injector. The injector connects to the upper mold through the central channel and is used to inject the mixed bone cement.
- Tightening clips. The tightening clips, made of polybutylene terephthalate (PBT), are inserted into the four lateral holes of the upper mold.

The upper and lower molds are coupled with the tightening clips and the injector is placed on the upper mold's central channel. The system is filled with low viscosity antibiotic polymethylmethacrylate bone cement (G3A 40 bone cement). After the cement cures, the temporary spacer is removed from the molds and placed into the joint place. The spacer remains in place (180 days or less) until the second stage of the two-stage procedure is performed to implant a conventional hip joint prosthesis.

The Acetabular Cup molds are available in the following configurations:

- Lower mold: Ø48 mm
- Upper molds: Ø52 mm, Ø56 mm, Ø60 mm

The implants molded from the subject device cups and the primary predicate acetabular cup (K191981) are of the same shape. The subject device worst case cup internal and external diameter are withing the range of the primary predicate cup (i.e., 46mm ID/54mm OD). Additionally both the subject device and primary predicate devices are molded with PMMA bone cement. And the only difference is that the subject device is molded before the surgery and the primary predicate Acetabular cup is already molded into a cup and provided in a sterile package. This difference does not raise questions of safety and effectiveness, since the company performed additional non-clinical testing and usability study.

VI. PERFORMANCE DATA

The performance and mechanical properties of the SpaceFlex Acetabular Cup were evaluated by bench testing according to the accepted standards and G21 acceptance criteria described below:

- Rupture Test, which determined the mechanical strength of the bone cement acetabular cup up to failure, to evaluate the compression strength of the bone cement acetabular cup under a ramp of load. The acceptance criteria of 400 N was successfully exceeded.

- Fatigue Test, conducted per ASTM 3090-20:2020 Standard Test Method for Fatugue Testing of Acetabular Devices for Total Hip Replacment, evaluated the fatigue strength of the bone cement acetabular cup. The results were compliant with the acceptance criteria of 500,000 cycles without a break.

- Wear Test, conducted per ISO 14242-1-2014 Implants for surgery – wear of total hip joing prostheses, which verified the wear behavior of the bone cement SpaceFlex Acetabular Cup made by G3A 40 bone cement and SpaceFlex Acetabular Cup molds. The results were compliant with the acceptance criteria of 500,000 cycles without a break.

- Gentamicin Elution Test, which determined, on different sizes (52 and 60 mm) of the SpaceFlex Acetabular Cup, the release behavior of Getamicin in controlled conditions and compared the results with a cylinder of G3A bone cement. The elution behavior profiles of the tested specimens were comperable with the elution behavior profile of the G3A bone cement cylinder.

- Molding Temperature Analysis Test, which monitored the temperature of the SpaceFlex Acetabular Cup mold used to house the polymerization of a bone cement to verify that it did not exeed the maximum tolerable temperture of the material of which the molds are made corresponding to 120° C. The tested sample did not reach or exceed the maximum temperature limit of 120°C during the cement polyerization process.

VII. SUBSTANTIAL EQUIVALENCE

The SpaceFlex Acetabular cup is substantially equivalent to other legally marketed predicate devices. The SpaceFlex Acetabular Cup has the same general intended use and substantially the same indications for use as that of the previously cleared primary predicate REMEDY Acetabular Cup (K191981 / K173967).

The performance testing – mechanical/bench testing – as well as the same indications for use and materials demonstrate that the SpaceFlex Acetabular Cup is as safe and effective as its predicate devices.

VIII. BIOCOMPATIBILITY

The components of the SpaceFlex Acetabular Cup molds submitted as part of this submission do not come in contact with the patient. There are no patient-contacting device components. The molds are used only to mold the cement without coming in direct contact with the patient.

The molds that are the subject of this submission utilize the same mold materials (using the same manufacturing processes) as those for the previous submission K190216 (SpaceFlex Knee); therefore, we use the previously submitted data for that submission: FTIR-ATR analysis.

The FTIR-ATR Analysis on polymer matrix was performed on a not-aged and an after-accelerated ageing device. The activity focused on the analysis of the IR spectra acquired in ATR mode on the surface of the samples before and after polymerization of a polymer cement inside a SpaceFlex mold. The results show that there is no evidence of chemical modifications on the surface of the cement after curing in contact with the mold.

IX. CONCLUSION

The technological differences between the subject device and the predicate do not raise new questions of safety and effectiveness. Any minor differences in technological characteristics have been tested and documented.