February 17, 2021

G21 S.r.l.
% Barry Sands
President and Founder
RQMIS, Inc.
110 Haverhill Road, Suite 524
Amesbury, Massachusetts 01913

Re: K202338
Trade/Device Name: SpaceFlex Shoulder
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) Bone Cement
Regulatory Class: Class II
Product Code: MBB, HSD, KWS
Dated: November 13, 2020
Received: November 19, 2020

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,

Pooja Panigrahi -S

for

Laura C. Rose, Ph.D.
Assistant 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202338

Device Name
SpaceFlex Shoulder

Indications for Use *(Describe)*
Disposable cement spacer molds with metal reinforcement stem are indicated for use to mold a temporary hemi-shoulder replacement for skeletally mature patients undergoing a two-stage revision procedure due to a septic process.

The temporary prosthesis is molded using low viscosity polymethylmethacrylate bone cement and inserted into the humeral medullary canal and glenoid cavity of the shoulder following removal of the existing humeral and glenoideal cavity implants and debridement. SpaceFlex Shoulder should only be used with G3A low-viscosity bone cement.

The device is intended for use in conjunction with systemic antimicrobial antibiotic therapy (standard treatment approach to an infection).

The hemi-shoulder prosthesis made from the SpaceFlex Shoulder disposable cement molds is not intended for use more than 180 days, at which time it must be explanted and permanent devices implanted or another appropriate treatment performed (e.g. resection arthroplasty, fusion, etc.).

Due to the inherent mechanical limitations of the hemi-shoulder prosthesis material (low viscosity polymethylmethacrylate), the temporary hemi-shoulder prosthesis is only indicated for patients who will consistently follow activity limitation throughout the implant period.

The device can exclusively be used by competent healthcare personnel who has complete scientific and anatomical knowledge.

For what concerns the modes of usage of the bone cement potentially loaded with antibiotics, see the instructions for use of the selected bone cement.

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

G21 S.r.l. 's SpaceFlex Shoulder 510k Submission

I. SUBMITTER

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Date Prepared: 22 July 2020

II. DEVICE

Trade/Device Name:	SpaceFlex Shoulder
Common or Usual Name:	Temporary Shoulder Prosthesis
Classification Name:	Polymethylmethacrylate (PMMA) bone cement, antibiotic shoulder joint humeral polymer/metal/polymer semi-constrained cemented prosthesis
Regulation Number:	21 CFR 888.3027
Regulatory Class:	Class II
Product codes	MBB, KWS

III. PREDICATE DEVICES

Predicate Device:	Interspace Temporary Shoulder Spacer with Gentamicin (K112983) StageOne Disposable Cement Spacer molds for making temporary Hemi-Shoulder prosthesis (K160071)
Reference Devices:	Spaceflex Hip (K192041)

IV. DEVICE DESCRIPTION

Indications for Use / Intended Use:

Disposable cement spacer molds with metal reinforcement stem are indicated for use to mold a temporary hemi- shoulder replacement for skeletally mature patients undergoing a two-stage revision procedure due to a septic process.

The temporary prosthesis is molded using low viscosity polymethylmethacrylate bone cement and inserted into the humeral medullary canal and glenoid cavity of the shoulder following removal of the existing humeral and glenoideal cavity implants and debridement. SpaceFlex Shoulder should only be used with G3A low-viscosity bone cement.

The device is intended for use in conjunction with systemic antimicrobial antibiotic therapy (standard treatment approach to an infection).

The hemi-shoulder prosthesis made from the SpaceFlex Shoulder disposable cement molds is not intended for use more than 180 days, at which time it must be explanted and permanent devices implanted or another appropriate treatment performed (e.g. resection arthroplasty, fusion, etc.).

Due to the inherent mechanical limitations of the hemi-shoulder prosthesis material (low viscosity polymethylmethacrylate), the temporary hemi-shoulder prosthesis is only indicated for patients who will consistently follow activity limitation throughout the implant period.

The device can exclusively be used by competent healthcare personnel who has complete scientific and anatomical knowledge.

For what concerns the modes of usage of the bone cement potentially loaded with antibiotics, see the instructions for use of the selected bone cement.

V. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The SpaceFlex Shoulder and its predicate, Interspace Temporary Shoulder Spacer with Gentamicin, have the same intended use and indications for use, technological characteristics and principle of operation. The differences between the molds in the subject and the predicate device do not raise any significant new risks. Through performance and mechanical testing and material information it has been established that these differences do not present any new issues of safety or effectiveness

VI. PERFORMANCE DATA

The mechanical properties of the SpaceFlex Shoulder were tested in accordance with applicable international standards. In all instances the device functioned as intended and all results were satisfactory and met all performance specifications. The testing performed includes,

1. Fatigue Test
2. Visual Inspection and Dimensional Characterization Test
3. Usability Test
4. Gentamicin Elution Test

Performance testing showed equivalent performance to the K112983 predicate device.

VII. CONCLUSION

The SpaceFlex Shoulder disposable cement spacer is substantially equivalent to other legally marketed cement spacers indicated for use to mold a temporary total shoulder replacement. The SpaceFlex Shoulder has the same general intended use and substantially the same indications for use, technological characteristics, and principles of operation as the previously cleared predicate, Interspace Temporary Shoulder Spacer with Gentamicin (K112983) and additional predicate device, StageOne Disposable Cement Spacer molds for making temporary Hemi-Shoulder prosthesis (K160071).

The substantial equivalence discussion included in the submission demonstrates the substantial equivalence of the SpaceFlex Shoulder System (the subject device) and its predicate devices as well as describing the minor differences in the technological characteristics, which do not raise any new questions of safety or efficacy. The performance testing – mechanical/bench testing – as well as the same indications for use demonstrate that the SpaceFlex Shoulder system is as safe and effective as its predicate devices.