September 15, 2025

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

Re: K252443
Trade/Device Name: SpaceFix Shoulder Spacer
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KWS, MBB
Dated: August 1, 2025
Received: August 4, 2025

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

JESSE MUIR -S Digitally signed by JESSE MUIR -S
Date: 2025.09.15 12:03:35 -04'00'

Jesse Muir, 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252443

Please provide the device trade name(s).

SpaceFix Shoulder Spacer

Please provide your Indications for Use below.

The SpaceFix Shoulder Spacer is intended for temporary (maximum 180 days) use as part of a two-stage procedure in skeletally mature patients undergoing a total or hemi shoulder arthroplasty revision due to prosthetic joint infection.

The device is indicated for use when the infecting organism is sensitive to gentamicin, as the PMMA bone cement includes gentamicin for local antibiotic delivery.

Following prosthesis explantation and thorough debridement, the device is implanted in the glenoid cavity and humeral canal.

At the conclusion of the temporary implantation period (not to exceed 180 days), the device must be removed and either replaced with a definitive shoulder prosthesis or alternative surgical intervention (e.g., resection arthroplasty, fusion).

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

G21's SpaceFix Shoulder Spacer

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

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Date Prepared: July 31, 2025

B. SUBJECT DEVICE

Trade/proprietary name of device:	SpaceFix Shoulder Spacer
Common or Usual Name:	SpaceFix Shoulder Spacer
Classification Name:	Shoulder Joint metal/polymer semi-constrained cemented prosthesis
Regulation Number:	21 CFR 888.3660
Classification:	Class II
Product Code:	KWS, MBB

C. PREDICATE DEVICES

Primary Predicate:

- Name: SpaceFlex Shoulder
- 510(k): K202338
- Product code: KWS, MBB
- Regulation: 21 CFR 888.3027
- Classification: Class II

Additional Predicate:

- Name: Remedy Shoulder Spacer
- 510(k): K152267
- Product code: KWS, MBB
- Regulation: 21 CFR 888.3660
- Classification: Class II

D. DEVICE DESCRIPTION

The SpaceFix Shoulder Spacer is a temporary shoulder spacer made with PMMA bone cement with Gentamicin and reinforced with a stainless steel core. The subject device is provided sterile, single use and is intended for temporary (maximum 180 days) use as part of a two-stage procedure in skeletally mature patients undergoing total or hemi shoulder arthroplasty revision due to prosthetic joint infection.

E. INDICATIONS FOR USE

The SpaceFix Shoulder Spacer is intended for temporary (maximum 180 days) use as part of a two-stage procedure in skeletally mature patients undergoing total or hemi shoulder arthroplasty revision due to prosthetic joint infection.

The device is indicated for use when the infecting organism is sensitive to gentamicin, as the PMMA bone cement includes gentamicin for local antibiotic delivery.

Following prosthesis explantation and thorough debridement, the device is implanted in the glenoid cavity and humeral canal. At the conclusion of the temporary implantation period (not to exceed 180 days), the device must be removed and either replaced with a definitive shoulder prosthesis or alternative surgical intervention (e.g., resection arthroplasty, fusion).

F. TECHNOLOGICAL CHARACTERISTICS

The SpaceFix Shoulder Spacer is available in four different sizes, based on stem and head diameter, and stem length. The bone cement used to mold the SpaceFix Shoulder Spacer is the G3A formula, a low-viscosity bone cement that is already FDA approved. The reinforcement core used within the Spacer is made of stainless steel, as per the AISI 316LVM standard, and is identical to that of the primary predicate, SpaceFlex Shoulder.

G. PERFORMANCE DATA

Performance data was conducted to demonstrate that the performance of the SpaceFix Shoulder Spacer complies with the recognized consensus standards and G21 acceptance criteria. The tests include biocompatibility testing, shelf-life testing, sterilization validation, pyrogenicity testing/endotoxin monitoring, gentamicin elution profile assessment, fatigue strength testing, package integrity testing, and gentamicin stability. The company conducted the same test as the predicate, and found to be substantially equivalent to the primary predicate.

H. TECHNOLOGICAL CHARACTERISTICS COMPARISON:

The Subject Device, SpaceFix Shoulder Spacer, is substantially equivalent to the primary predicate, SpaceFlex Shoulder, K202338, in terms of indication and intended use, material and technological characteristics, and additional predicate, Remedy Shoulder Spacer, K152267, regarding molding process. The only difference is that the subject device, is premolded compared to the primary predicate, which is molded in the OR. This difference does not raise any questions of safety or effectiveness since the molding process is same and the performance of the subject device was found to be equivalent to the primary predicate device.

I. SUBSTANTIAL EQUIVALENCE CONCLUSION

Both the subject device and predicate bone cements are made of polymethylmethacrylate (PMMA) with gentamicin and are used for identical indications (i.e., for revision surgeries). Since there is no significant difference in the technological characteristics between the subject and predicate devices, we conclude that the subject device is substantially equivalent to the Primary Predicate (K202338).