March 19, 2020

G21 S.r.1
% Mr. Barry Sands
President and Founder
RQMIS, Inc.
110 Haverhill Road, Suite 526
Amesbury, Massachusetts 01913

Re: K193059/S001
Trade/Device Name: G1 40 Radiopaque Bone Cement
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) Bone Cement
Regulatory Class: Class II
Product Code: LOD
Dated: February 5, 2020
Received: February 7, 2020

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,

for

Jesse Muir, Ph.D.
Acting 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)*
K193059

Device Name
G1 40 Radiopaque Bone Cement

Indications for Use *(Describe)*
G1 40 Radiopaque Bone Cement is intended for use in arthroplasty procedures of the hip, knee, ankle, shoulder and other joints for the fixation of polymer or metallic prosthetic implants to living bone.

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 G1 40 Radiopaque Bone Cement 510k Submission

I. SUBMITTER

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II. DEVICE

Trade/Device Name:	G1 40 Radiopaque Bone Cement
Common or Usual Name:	Bone cement
Classification Name:	Polymethylmethacrylate (PMMA) bone cement
Regulation Number:	21 CFR 888.3027
Regulatory Class:	Class II
Product codes	LOD

III. PREDICATE DEVICES

Primary Predicate Device:	Heraeus Kulzer Palacos R (K030902)
Additional Predicate:	G21 OrthoSteady G (K173494)

IV. DEVICE DESCRIPTION

Intended Use:

G1 40 Radiopaque Bone Cement is intended for use in arthroplasty procedures of the hip, knee, ankle, shoulder and other joints for the fixation of polymer or metallic prosthetic implants to living bone.

Indications for Use:

G1 40 Radiopaque Bone Cement is intended for use in arthroplasty procedures of the hip, knee, ankle, shoulder and other joints for the fixation of polymer or metallic prosthetic implants to living bone.

V. SUBSTANTIAL EQUIVALENCE

Technological Comparison

The subject device has similar technological characteristics as the predicate devices. Both predicates and subject device provide two separate, premeasured sterilized components which, when mixed, form a radiopaque rapidly setting bone cement. The subject device and the predicate devices are all polymethylmethacrylate (PMMA) bone cements.

The packaging configuration (powder pouches, amber glass ampoule) for the subject device is identical to the predicate device.

The sterilization method for the powder of the subject device is identical to the predicate device. The sterilization method for the liquid component of the subject device is identical to predicate device.

Therefore, the subject device has the same design, intended use and mode of operation as the predicate.

Performance Comparison

The following performance data are provided in support of the substantial equivalence determination.

- **Biocompatibility**
  According to its categorization and ISO 10993-1 recommendations, biological effects that have been considered as per categorization of the predicate and then suitable for G1 40 Radiopaque Bone Cement include cytotoxicity, sensitization, intracutaneous reactivity, systemic toxicity, pyrogen, AMES, LAL, and bone implantation toxicity and effects.

As recommended by the FDA's Guidance "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing', the subject devices and predicates comply with ISO 10993 at parts -3, -5, -6, -10, -11.

- **Sterilization**
  The sterilization process, including both the ethylene oxide method (powder component and aseptically processed, filled glass vials) as well as the membrane filter-sterilization (liquid component), has been validated and the sterility of the subject devices has been verified according to ISO 11135:2014, ISO 11138-1:2006, ISO 10993-7:2009, ISO 14161:2009, ISO 14937:2009, ISO 11737-1:2006, ISO 11737-2:2009, ISO 13408-1:2008, and ISO 13408-2:2003.

  The shelf life of the G1 40 Radiopaque Bone Cement is three years.

- **Material, Mechanical and Performance Characterization**
  Performance testing of compressive strength, bending strength, bending modulus, cyclic fatigue, tensile properties, creep, fracture toughness, and shrinkage was conducted to characterize G1 40 Radiopaque Bone Cement as compared to the predicate, according to the FDA's Guide "Class II Special Controls Guidance Document: polymethylmethacrylate (PMMA) Bone Cement; Guidance for Industry and FDA". Results show comparable performances to the predicate devices, and are in compliance with ASTM F451-08, ISO 5833:2002, ASTM F2118-14, ASTM D2990-09, ASTM D638-14, and ASTM E399-12.

  In all instances the device functioned as intended and all results were satisfactory and met all performance specifications.

VI. CONCLUSION

The G1 40 Radiopaque Bone Cement is as safe and effective as the primary predicate Heraeus Kulzer Palacos R (K030902) and the additional predicate G21 OrthoSteady G (K173494). The G1 40 Radiopaque Bone Cement has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor technological differences between the G1 40 Radiopaque Bone Cement and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the G1 40 Radiopaque Bone Cement is as safe and effective as Heraeus Kulzer Palacos R (K030902) and G21 OrthoSteady G (K173494). Thus, the G1 40 Radiopaque Bone Cement is substantially equivalent.