March 6, 2018

G21 s.r.l.
% Mr. Barry E. Sands
President
RQMIS, Inc.
110 Haverhill Road, Suite 526
Amesbury, Massachusetts 01913

Re: K173494
Trade/Device Name: OrthoSteady G Bone Cement
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: Class II
Product Code: LOD, MBB
Dated: January 29, 2018
Received: February 1, 2018

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ronald P. Jean -S

for Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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)*
K173494

Device Name
OrthoSteady G Bone Cement

Indications for Use *(Describe)*
OrthoSteady G Bone Cement is indicated for use in the second stage of a two-stage revision for total joint arthroplasty after the initial infection has been cleared.

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.

OrthoSteady G Bone Cement

1. General Information

Submitter:	G21 srl via S. Pertini, 8 41039 San Possidonio (MO)- ITALY Phone: +39 0535 30312 Fax: +39 0535 417332
Official contact:	Barry E. Sands Phone: 978-358-7307 Fax: 978-358-7384
Summary Preparation Date:	January 29, 2018

2. Device

Device Name:	OrthoSteady G Bone Cement
Common name:	Bone Cement, Antibiotic
Classification name:	888.3027 - PMMA bone cement
Classification number:	Class II
Product Code:	LOD MBB

3. Predicate Devices

Primary
PALACOS R+G Bone Cement device (Heraeus Kulzer GMBH & Co. KG) – K031673

Additional
DePuy CMWTM 1 Gentamicin Bone Cement (DePuy Orthopaedics) - K053002

4. Indications for use/Intended Use

Indication for Use:

OrthoSteady G Bone Cement is indicated for use in the second stage of a two stage revision for total joint arthroplasty after the initial infection has been cleared.

5. Summary of the technological characteristics of the subject devices compared to the predicate

The OrthoSteady G Bone Cement consists of Gentamicin sulphate antibiotic and a two component system consisting of separate, sterile and liquid powder components. All the materials (including the liquid and powder components) are within the range and covered by the predicate device.

6. Biocompatibility

According to its categorization and ISO 10993 – 1 recommendations, biological effects that have been considered as per categorization of G1A and then suitable for OrthoSteady G 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.

7. Sterilization

The sterilization process, including both the ethylene oxide method (packaged, aseptically processed, filled glass vials), gamma irradiation (packaged powder), and 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.

8. Performance data

Performance testing of compressive strength, bending strength, bending modulus, cyclic fatigue, tensile properties, creep, fracture toughness, and shrinkage was conducted to characterize OrthoSteady G 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.

9. Conclusion and SE Determination

The OrthoSteady G Bone Cement is as safe and effective as the PALACOS R+G Bone Cement device (Heraeus Kulzer GMBH & Co. KG). The OrthoSteady G 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 OrthoSteady G Bone Cement and its predicate device raise no new issues of safety or effectiveness. Performance data demonstrates that the OrthoSteady G

Bone Cement is as safe and effective as the PALACOS R+G Bone Cement device (Heraeus Kulzer GMBH & Co. KG). The OrthoSteady G Bone Cement is substantially equivalent to the predicate devices.