June 9, 2019

G21 S.r.l
% Manjusha Bharadwaj
Regulatory/Quality Consultant
RQMIS, Inc.
110 Haverhill Road, Suite 526
Amesbury, Massachusetts 01913

Re: K190216
Trade/Device Name: G21 s.r.l SpaceFlex Knee
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: Class II
Product Code: MBB, JWH
Dated: March 5, 2019
Received: March 11, 2019

Dear Manjusha Bharadwaj:

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,

Laurence D. Coyne, 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)*
K190216

Device Name
G21 s.r.l SpaceFlex Knee

Indications for Use *(Describe)*

Disposable cement spacer molds are indicated for use to mold a temporary total knee replacement (TKR) for skeletally mature patients undergoing a two stage procedure due to a septic process. The molded temporary knee prosthesis is indicated for an implantation period of 180 days or less. Because of inherent mechanical limitations of the device material (G3A 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

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

I. SUBMITTER

G21 S.r.l.
Via S. Pertini, 8
41039 S. Possidonio (MO) Italy

Phone: +39 0535 30312
Fax: +39 0535 417332

Contact Person:
Manjusha Bharadwaj
Senior Quality/Regulatory Consultant
RQMIS, Inc.
110 Haverhill Road, Suite 526
Amesbury, MA 01913
Phone: 1-(978) 358-7307
Fax: 1 (978) 477-0206

Date Prepared: 01 October 2018

II. DEVICE

Trade/Device Name:	SpaceFlex Knee
Common or Usual Name:	Temporary Knee Prosthesis
Classification Name:	Polymethylmethacrylate (PMMA) bone cement, antibiotic
	Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulation Number:	21 CFR 888.3027, 21 CFR 888.3560
Regulatory Class:	Class II
Product codes	MBB, JWH

III. PREDICATE DEVICES

Primary Predicate: StageOne Disposable Cement Spacer Molds for Temporary Knee Prosthesis, Biomet, Inc. (K161273)

Additional Predicates: SPACER-K Temporary Knee Prosthesis, Tecres S.p.A. (K062274), OsteoRemedies Knee Modular Spacer (K112470, filed under Garventis LLC Ronald Reagan and International Trade Center)

IV. DEVICE INFORMATION

Device Description:

G21 SpaceFlex Knee system are disposable cement spacer molds made of polypropylene (PP) intended to be filled with low-viscosity polymethyl methacrylate bone cement directly in the operating room. Once the bone cement has hardened, the SpaceFlex Knee system creates a polymethyl methacrylate based bone cement spacer for patients undergoing a two-stage procedure following a periprosthetic joint infection. The device can be used in either the left or right knee joint. The SpaceFlex Knee molds are single-use and cannot be re-used or re-sterilized.

Intended Use:

SpaceFlex Knee is a mold intended to assist in the creation of a temporary disposable cement spacer for a total knee replacement (TKR) for skeletally mature patients undergoing a two-stage procedure due to a septic process.

Indications for Use:

SpaceFlex Knee disposable cement spacer molds are indicated for use to mold a temporary total knee replacement (TKR) for skeletally mature patients undergoing a two-stage procedure due to a septic process. The molded temporary knee prosthesis is indicated for an implantation period of 180 days or less. Because of inherent mechanical limitations of the device material (G3A 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. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The technological features of the SpaceFlex Knee are similar to the predicates with one difference in the materials used for the manufacturing of the molds. The material used in the SpaceFlex Knee molds is medical grade polypropylene widely used in medical syringes and the predicate device molds are made of medical grade silicone.

Performance testing was completed on the SpaceFlex Knee device in accordance with established international standards to establish the mechanical properties and gentamicin release profile of the device. The results of the performance testing demonstrated that the SpaceFlex Knee device possess mechanical and elution characteristics equivalent to those of the predicate device. Specifically, the gentamicin release profile for the SpaceFlex Knee spacers was compared to the predicate device OsteoRemedies Knee Modular Spacer (K112470). The cumulative gentamicin release from SpaceFlex Knee was compared at time intervals of day 1, week 1 and week 2 to the predicate device's (OsteoRemedies Knee Modular Spacer (K112470)) gentamicin release profile available from the predicate labeling documents. The comparison of this data evaluated that the

cumulative release of gentamicin from the SpaceFlex Knee spacer is substantially equivalent to the additional predicate device OsteoRemedies Knee Modular Spacer (K112470).

Based on the comparison data of the mechanical properties and the gentamicin release profile, the subject device and predicate device are similar in design, fundamental scientific technology and comparable gentamicin elution profile. The minor differences between the subject and predicates do not lead to new safety or effectiveness issues.

VI. PERFORMANCE DATA

The mechanical properties of the SpaceFlex knee System 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. Rupture Test
2. Fatigue Test
3. Gentamicin Elution Test
4. The Wear Test – Mechanical performance
5. Molding Temperature Analysis
6. Residual Analysis on Polymer Matrix

VII. CONCLUSION

The SpaceFlex knee disposable cement spacer is substantially equivalent to other legally marketed cement spacers indicated for use to mold a temporary total knee replacement.
The SpaceFlex knee has the same general intended use and substantially the same indications for use, technological characteristics, and principles of operation as the previously cleared primary predicate StageOne Disposable Cement Spacer Molds for Temporary Knee Prosthesis, Biomet, Inc. (K161273) and additional predicates SPACER-K Temporary Knee Prosthesis, Tecres S.p.A. (K062274) and OsteoRemedies Knee Modular Spacer (K112470).

The substantial equivalence discussion included in the submission demonstrates the substantial equivalence of the SpaceFlex Knee 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 indications for use, performance testing – mechanical/bench testing and gentamicin elution release profile of the SpaceFlex Knee Spacer are comparable to the primary as well as the additional predicates listed above and the data presented demonstrate that the SpaceFlex Knee system is substantially equivalent to its predicate devices.