August 13, 2020

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

Re: K201960
Trade/Device Name: SpaceFlex Knee – 80mm Size
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWH, MBB
Dated: July 10, 2020
Received: July 14, 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,

for

Laura C. Rose, 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)*
K201960

Device Name
SpaceFlex Knee - 80mm Size

Indications for Use *(Describe)*
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.

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.

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510(k) SUMMARY

G21 ‘s SpaceFlex 80mm size 510k Submission (K201960)

I. SUBMITTER

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Date Prepared: February 12, 2020

II. DEVICE

Trade/Device Name:	SpaceFlex Knee – 80mm Size
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: SpaceFlex Knee, G21 S.R.L. (K190216)

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

IV. 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

Both the subject device and the predicate device are disposable cement spacer molds with two separate molds – femoral and tibial. The subject devices possess identical technical characteristics as the primary predicate. The only difference between subject and predicate devices is a larger dimensional footprint.

The technological features of the SpaceFlex Knee are the same as the primary predicate device.

VI. PERFORMANCE DATA

The mechanical properties of the SpaceFlex knee System 80mm size 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. Dimensional and Visual Characterization
2. Rupture Test
3. Fatigue Test
4. Elution Test

VII. CONCLUSION

The SpaceFlex Knee – 80mm and its primary predicate, G21 SpaceFlex Knee system, have the same intended use and indications for use, technological characteristics and principle of operation. The material 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. The SpaceFlex Knee – 80mm is substantially equivalent to the primary predicate, G21 SpaceFlex Knee System, and additional predicate StageOne Disposable Cement Spacer Molds for Temporary Knee Prosthesis.