May 19, 2022

Ormed Grup Medikal Turizm Saglik Hizmetleri Sanayi Ve
℅ Mehmet Ormeci
Consultant
Medcer Uluslararasi Medikal Belgelendirme Anonim Sirketi
Taspinar Mahallesi 2800. Caddesi A-2 Apt. No:6 B/49
Ankara, 06830
Turkey

Re: K211869
Trade/Device Name: OGM® 1
OGM® 1A
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) Bone Cement
Regulatory Class: Class II
Product Code: LOD, MBB
Dated: March 28, 2022
Received: April 8, 2022

Dear Mehmet Ormeci:

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.
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)*
K211869

Device Name
OGM® 1

Indications for Use *(Describe)*
OGM® 1 is a PMMA bone cement intended for use in arthroplastic procedures of the hip, knee 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.

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."

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)*
K211869

Device Name
OGM® 1A

Indications for Use *(Describe)*
OGM® 1A 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)

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510(k) Summary

510(k) Submitter Name	ORMED GRUP SAGLIK MEDIKAL TURIZM SAGLIK HIZMETLERI SANAYI VE TICARET LTD. STI.
510(k) Submitter Adress	Macun Mahallesi 177 Sokak No:19 H/7b Yenimahalle, Ankara, TURKEY
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Summary Preparation Date	03/28/2022

Trade Or Proprietary Name	OGM® 1, OGM® 1A
Common Name	PMMA Bone Cement
Classification Name	Bone Cement
Regulation Name	Polymethylmethacrylate (PMMA) bone cement
Regulation Number	21 CFR 888.3027
Product Code	LOD, MBB
Regulatory Class	Class II

Subject Device 510k No	Primary Predicate Device 510k No	Primary Predicate Device Manufacturer
OGM® 1 K211869	PALACOS® R K202475	Heraeus Medical GmbH Philipp-Reis-Str. 8/13 61273 Wehrheim Germany
OGM® 1A K211869	PALACOS® R+G K202475	Heraeus Medical GmbH Philipp-Reis-Str. 8/13 61273 Wehrheim Germany

Subject Device 510k No	Seconder Predicate Device 510k No	Primary Predicate Device Manufacturer
OGM® 1A K211869	DePuy 1 Gentamicin Bone Cement K023103	DePuy, Inc. 700 Orthopaedic Drive Warsaw, IN 46581

Device Description:

A bundled Traditional 510(k) submission is being supplied to the U.S. FDA to gain clearance for modifications to OGM® 1 and OGM® 1A®. This submission encompasses multiple devices that have similar intended use and indications for use as well as rely on similar data.

OGM® bone cements without Gentamicin

OGM® 1 is polymethylmethacrylate (PMMA) bone cement:

- OGM® 1: is a standard-setting, high-viscosity, PMMA-based bone cement for orthopaedic surgery,

The OGM® 1 consists of two components, a monomer liquid and a polymer powder. The liquid component contains the monomer, accelerator, and a stabilizer. The powder contains the polymer, X-Ray-opacifier, and initiator. They are intended for single-use and are provided sterile (ethylene oxide and sterile filtration).

OGM® bone cements with Gentamicin

OGM® 1A is polymethylmethacrylate (PMMA) bone cement, containing the antibiotic Gentamicin:

- OGM® 1A is a standard-setting, high-viscosity, PMMA-based bone cement for orthopaedic surgery,

The OGM® 1A consists of two components, a monomer liquid and a polymer powder. The liquid component contains the monomer, accelerator, and a stabilizer. The powder contains the polymer, X-Ray-opacifier, initiator and the antibiotic Gentamicin. They are intended for single-use and are provided sterile (ethylene oxide and sterile filtration).

Indications For Use:

OGM® 1 is a PMMA bone cement intended for use in arthroplastic procedures of the hip, knee and other joints for the fixation of polymer or metallic prosthetic implants to living bone.

OGM® 1A is indicated for use in the second stage of a two-stage revision for total joint arthroplasty after the initial infection has been cleared.

Comparison of technological characteristics:

OGM® 1

Device comparison demonstrated that the OGM® 1 is substantially equivalent to the previously cleared PALACOS® R (K202475) regarding intended use, technological characteristics (device design, material and performance) as well as operating principle. At a high level, the subject device and predicate device are based on the following same or similar technological elements:

- PMMA bone cement (same),

- Chemical composition (similar),

- Sterilized with an established method (ethylene oxide) as per DIN EN ISO 11135-1 and DIN EN ISO 10993-7 (same),

- Side by side mechanical testing was performed according to the ISO 5833 and ASTM D732. The mechanical characteristics are similar when it is compared with predicate device.

- Mixing and application properties (same), and

- Clinical use of the devices including the anatomical location, duration of exposure (same) and intended use population (same).

Regarding chemical composition comparison, while the predicate device contains zirconium dioxide, the subject device contains barium sulfate in the cement powder as an X ray contrast medium. Both materials are used in commercialized bone cements as an X ray contrast medium. Chemical formulas between predicate device and subject device have slight differences. The predicate device contains chlorophyll additive serves as marking of the bone cement at the site of the operation. The subject device do not contain chlorophyll, but it is still visible as off white instead of green which chlorophyll provides for predicate device.

OGM® 1A

Device comparison demonstrated that the OGM® 1A is substantially equivalent to the previously cleared PALACOS® G (K202475) and DePuy 1 Gentamicin Bone Cement (K023103) regarding intended use, technological characteristics (device design, material and performance) as well as operating principle. At a high level, the subject device and predicate device are based on the following same or similar technological elements:

- PMMA bone cement (same),

- Chemical composition (similar),

- Sterilized with an established method (ethylene oxide) as per DIN EN ISO 11135-1 and DIN EN ISO 10993-7 (same),

- Side by side mechanical testing was performed according to the ASTM F2118, ISO 5833 and ASTM D732. The mechanical characteristics are similar when it is compared with predicate device (K023103).

- Mixing and application properties (same) and

- Clinical use of the devices including the anatomical location, duration of exposure (same), and intended use population (same).

- 1g Gentamicin is utilized to powder (similar for primary predicate and same for secondary predicate).

- Gentamicin release profiles are compared with the secondary predicate device (K023103) and no significant difference was observed.

Discussion of Non-Clinical Tests:

For the OGM® 1 and OGM® 1A bone cements the stability of liquid component, maximum temperature, setting time, intrusion, compressive strength, bending modulus and bending strength of was characterized per ISO 5833.

Mechanical tests were also performed according to ASTM D732, ASTM F2118 standards. ASTM F451 requirements are met.

ATCC antibacterial efficiency testing was performed to OGM 1A.

Endotoxin testing was performed to OGM® 1 and OGM® 1A according to USP Endotoxin Reference Standard. The results meet the limit value (20 EU/device).

EtO sterilization was validated per ISO 11135.

Biocompatibility testing, including cytotoxicity, irritation, sensitization, acute systemic toxicity, sub-acute systemic toxicity, implantation and genotoxicity was performed per ISO 10993. Because OGM® 1A can be regarded as worst case product, the results are also valid for OGM® 1.

Substantially Equivalence Discussion

	Subject Device **K211869**	**Predicate Device** **K202475**	**Comparison**
Manufacturer	OGM	Heraeus	-
Device Name	OGM® 1	Palacos® R	-
Intended Use	OGM® 1 is a PMMA bone cement intended for use in arthroplastic procedures of the hip, knee and other joints for the fixation of polymer or metallic prosthetic implants to living bone.	Palacos® R is indicated for use in arthroplastic procedures of the hip, knee, and other joints for the fixation of polymer or metallic prosthetic implants to living bone.	same
Components	40g powder (polymer) and 20ml liquid (monomer) is individually packed.	40g powder (polymer) and 20ml liquid (monomer) is individually packed.	same
Sterilization	ethylene oxide and sterile filtration	ethylene oxide and sterile filtration	same
Contact Duration	Permanent / implantable	Permanent / implantable	same
Powder Mass	40g	40g	same
Liquid Volume	20ml	20ml	same
Powder Chemical Composition	poly(methyl acrylate, methyl methacrylate) 35.6 g	poly(methyl acrylate, methyl methacrylate) 33.8 g	**similar**
	Barium sulfate 4 g	zirconium dioxide 5.9 g	**similar**
	hydrous benzoyl peroxide 0.4 g	hydrous benzoyl peroxide 0.3 g	**similar**
	-	chlorophyll VIII trace amount	**different**
Liquid Chemical Composition	methyl methacrylate 19.6 g	methyl methacrylate 18.4 g	**similar**
	N,N-dimethyl-p-toluidine 0.4 g	N,N-dimethyl-p-toluidine 0.4 g	Same
	-	liquid: chlorophyll VIII in an oily solution trace amount	**different**
	Hydroquinone trace amount	Hydroquinone trace amount	same

Regarding chemical composition comparison, while the predicate device contains zirconium dioxide, the subject device contains barium sulfate in the cement powder as an X ray contrast medium. Both materials are used in commercialized bone cements as an X ray contrast medium. Chemical formulas between predicate device and subject device have slight differences. The predicate device contains chlorophyll additive serves as marking of the bone cement at the site of the operation. The subject device do not contain chlorophyll, but it is still visible as off white instead of green which chlorophyll

provides for predicate device. Subject device has been carried out the ISO 5833 performance tests and ISO 10993 biocompatibility tests. ISO 5833 requirements are fulfilled. ISO 10993 test results demonstrates biological safety. Endotoxin testing was performed to OGM® 1 according to USP Endotoxin Reference Standard. The results meet the limit value (20 EU/device).

Substantially Equivalence Discussion

	Subject Device K211869	Primary Predicate Device K202475	Secondary Predicate Device K023103	Primary Comparison	Secondary Comparison
Manufacturer	OGM	Heraeus	DePuy Synthes	-	-
Device Name	OGM® 1A	Palacos® R+G	DePuy 1 Gentamicin Bone Cement	-	-
Intended Use	OGM® 1A is indicated for use in the second stage of a two-stage revision for total joint arthroplasty after the initial infection has been cleared.	Palacos® R+G is indicated for use in the second stage of a two-stage revision for total joint arthroplasty after the initial infection has been cleared.	DePuy 1 Gentamicin is indicated for use in the second stage of a two stage revision for total joint arthroplasty after the initial infection has been cleared.	same	same
Components	40g powder (polymer) and 20ml liquid (monomer) is individually packed.	40g powder (polymer) and 20ml liquid (monomer) is individually packed.	40g powder (polymer) and 20ml liquid (monomer) is individually packed.	same	same
Sterilization	ethylene oxide and sterile filtration	ethylene oxide and sterile filtration	ethylene oxide and sterile filtration	same	same
Contact Duration	Permanent / implantable	Permanent / implantable	Permanent / implantable	same	same
Powder Mass	40g	40g	40g	same	same
Liquid Volume	20ml	20ml	20ml	same	same
Powder Chemical Composition	poly(methyl acrylate, methyl methacrylate) 35.6 g	poly(methyl acrylate, methyl methacrylate) 33.6 g	poly(methyl acrylate, methyl methacrylate) 84.73 (%w/w)	**similar**	**similar**
	Barium sulfate 4 g	zirconium dioxide 6.1 g	Barium sulfate 9.10 (%w/w)	**similar**	**similar**
	hydrous benzoyl peroxide 0.4 g	hydrous benzoyl peroxide 0.3 g	hydrous benzoyl peroxide 1.95 (%w/w)	**similar**	**similar**
	gentamicin base (as sulphate) 1 g	gentamicin base (as sulphate) 0.5 g	gentamicin base (as sulphate) 1 g	**different**	same
	-	chlorophyll VIII trace amount	-	**different**	same
Liquid Chemical Composition	methyl methacrylate 19.6 g	methyl methacrylate 18.4 g	methyl methacrylate 98.50 (%w/w)	**similar**	**similar**
	N,N-dimethyl-p-toluidine 0.4 g	N,N-dimethyl-p-toluidine 0.4 g	N,N-dimethyl-p-toluidine < 1.50 (%w/w)	same	**similar**
	-	liquid: chlorophyll VIII in an oily solution trace amount	-	**different**	same
	Hydroquinone trace amount	Hydroquinone trace amount	Hydroquinone trace amount	same	same

Regarding chemical composition comparison, while the primary predicate device contains zirconium dioxide, the subject device contains barium sulfate in the cement powder as an X ray contrast medium. On the other hand, secondary predicate device contains barium sulfate as the subject device. Both materials are used in commercialized bone cements as an X ray contrast medium.

The subject device and secondary predicate device contain 1g gentamicin sulfate, on the contrary primary predicate device contains 0.5g gentamicin sulfate. Gentamicin sulfate is bactericidal and is active against many strains of Gram-positive and Gram-negative pathogens. As per gentamicin sulfate ratio is higher than the primary predicate device antibacterial efficacy can be considered as substantially equivalent to primary predicate device. Antibacterial efficacy tests are performed to subject device. On the other hand, release ratio of Gentamicin is important both in dosage and total release duration. OGM® 1A is subjected to Gentamicin release test comparatively with the predicate device**.** Lastly, gentamicin has a negative effect on product mechanical and physical properties. ISO 5833 tests are applied to OGM® 1A and demonstrated compliance.

Chemical formulas between predicate devices and subject device have slight differences. The primary predicate device contains chlorophyll additive serves as marking of the bone cement at the site of the operation. The subject device and secondary predicate device do not contain chlorophyll, but it is still visible as off white instead of green which chlorophyll provides for primary predicate device. Subject device has been carried out the ISO 5833 performance tests and ISO 10993 biocompatibility tests. ISO 5833 requirements are fulfilled. ISO 10993 test results demonstrates biological safety.

Endotoxin testing was performed to OGM® 1A according to USP Endotoxin Reference Standard. The results meet the limit value (20 EU/device).

Conclusion

The non-clinical tests comply with the requirement of ISO 5833 and ASTM F451. Biological safety has been demonstrated according to the ISO 10993-1. Side-by-side mechanical tests were also performed according to ASTM D732, ASTM F2118 standards and the results are similar when compared to predicate devices. Endotoxin testing was performed to OGM® 1 and OGM® 1A according to USP Endotoxin Reference Standard. The results meet the limit value (20 EU/device). Antibacterial efficiency testing was performed according to the AATC and it is showed that the device is efficient to the E.Coli. Gentamicin release profile is also tested side-by-side with predicate device and the results are similar when compared to predicate devices (K023103). The differences between the predicate devices and the subject device do not raise any new or different questions of safety or effectiveness. The subject devices are substantially equivalent to the predicate devices with respect to the indications for use, target populations, treatment method, and technological characteristics.