May 31, 2022

Biomecanica Indústria e Comérciode Produtos Ortopédicos LTDA
℅ Graziela Brum
Regulatory Affairs Specialist
Passarini Regulatory Affairs/PR Serviços Regulatórios Administrativos Ltda ME
Rua Alice Além Saadi, 855/2402
Ribeirão Preto, São Paulo 14096-570 Brazil

Re: K212729
Trade/Device Name: Bone Cement-Normal Viscosity
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) Bone Cement
Regulatory Class: Class II
Product Code: LOD
Dated: April 11, 2022
Received: April 20, 2022

Dear Graziela Brum:

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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212729

Device Name
Bone Cement - Normal Viscosity

Indications for Use *(Describe)*

Bone Cement - Normal Viscosity is indicated for fixation of prostheses to live bone in musculoskeletal orthopedic surgical interventions in cases of rheumatoid arthritis, osteoarthritis, traumatic arthritis, osteoporosis, avascular necrosis, collagen disease, severe secondary destruction of the joints after trauma or other conditions and in the review of previous arthroplasty procedures.

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.

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510(k) Summary

ADMINISTRATIVE INFORMATION

Sponsor/Manufacturer Name	Biomecanica Indústria e Comércio de Produtos Ortopédicos Ltda. Rua Luiz Pengo 145 Jaú, São Paulo, Brazil 17212-811 Telephone: +55 (14) 2104-7900
Contact Person and Preparer	Graziela Brum and Ana Carolina Carvalho Regulatory Affairs Specialist Passarini Regulatory Affairs PR Serviços Regulatórios Administrativos Ltda E-Mail: graziela@passarini.com.br Telephone +55 (11) 98578-0200
Date Prepared	30/May/2022

DEVICE NAME AND CLASSIFICATION

Trade/ Proprietary Name	Bone Cement - Normal Viscosity
Common Name	Bone Cement
Classification Name	Polymethyl Methacrylate (PMMA) Bone Cement
Product Code	LOD
Classification Regulation	21 CFR 888.3027; Class ll
Classification Panel	Orthopedic

PREDICATE DEVICE INFORMATION

Predicate Device	K053003 - DePuy CMW 3 Bone Cements, DePuy Orthopedics, Inc.

INDICATIONS FOR USE

Bone Cement - Normal Viscosity is indicated for fixation of prostheses to live bone in musculoskeletal orthopedic surgical interventions in cases of rheumatoid arthritis, osteoarthritis, traumatic arthritis, osteoporosis, avascular necrosis, collagen disease, severe secondary destruction of the joints after trauma or other conditions and in the review of previous arthroplasty procedures.

DEVICE DESCRIPTION

The Bone Cement – Normal Viscosity is a self-curing, radiopaque, polymethyl methacrylate-based cements used for securing a metal or polymeric prothesis to living bone in arthroplasty procedures. The bone cement has no intrinsic adhesive properties but rely instead on close mechanical interlock between the irregular bone surface and the prosthesis.

EQUIVALENCE TO MARKETED DEVICE

The Bone Cement – Normal Viscosity shares many of the same technological characteristics compared to the predicate DePuy CMW 1, 2 and 3 Bone Cements important considerations such as most materials. 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.

Table 1: Comparison of the Technological Characteristics with the Predicate Devices

Characteristics		**Subject Device**	**Predicate(K053003) Model: CMW3**
Bone Cement Powder:	Radio pacifier	Barium Sulphate	Barium Sulphate
	Polymer	Poly (methyl acrylate/methyl methacrylate) (PMMA)	Poly (methyl acrylate/methyl methacrylate) (PMMA)
	Initiator	Benzoyl Peroxide	Benzoyl Peroxide
	Colour additives	None	None
Bone Cement Liquid:	Monomer	Methylmethacrylat e (MMA) stabilized with Hydroquinone	Methylmethacrylat e (MMA) stabilized with Hydroquinone
	Activator	N, N-dimethyl-p toluidine	N, N-dimethyl-p toluidine

	Colour Additives	None	None

PERFORMANCE DATA

These 510(k) submissions provided performance data to establish the substantial equivalence of the new bone cements to the predicate bone cement. Performance testing was conducted in accordance with the "FDA Class II Special Controls Guidance Document: Polymethylacrylate (PMMA) Bone Cement; Guidance for Industry and FDA" dated July 17, 2002. Non-clinical performance testing was performed to characterize the bone cements in accordance with special controls guidance document. This testing included the following:

- Mixing and Application characteristics
- Chemical Composition
- Molecular weight
- Physical Properties
- Stability of Components
- Thermal Properties
- Mechanical properties

The performance data demonstrate that the new device Bone Cement – Normal Viscosity substantially equivalent to the predicate device application K053003.

Sterilization and Shelf Life: The sterilization process, including the ethylene oxide method and the membrane filter sterilization has been validated and the sterility of the subject device has been verified according to ISO 11135 and ISO 13408-1/2.

Endotoxins: The assessment on the presence of endotoxins was carried out in accordance with USP 43 - NF 38, 2020 <85> Bacterial Endotoxins Test.

Biocompatibility: The biological evaluation of subject device was performed in accordance with ISO 10993-1 in accordance with the "Biological evaluation of medical devices - Part 1: evaluation and testing within a risk management process", issued September 20202018."

No clinical data were included in this submission.

CONCLUSION

The documentation submitted in this premarket notification demonstrates that the subject device has comparable features and performance and, therefore, are substantially equivalent to the identified predicate device.