January 9, 2023

Tecres S.p.A.
% Christine Brauer, PhD
Regulatory Affairs Consultant
Brauer Device Consultant, LLC
7 Trail House Court
Rockville, Maryland 20850

Re: K211163
Trade/Device Name: Bone Cement Genta, Bone Cement HV, Bone Cement LV
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) Bone Cement
Regulatory Class: Class II
Product Code: LOD, MBB
Dated: December 7, 2022
Received: December 10, 2022

Dear Christine Brauer:

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,

Sara S. Thompson -S

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211163

Device Name
Bone Cement LV
Bone Cement HV

Indications for Use *(Describe)*
Bone Cement LV and HV are indicated for the fixation of joint prostheses to living bone in orthopedic musculoskeletal surgical procedures for rheumatoid arthritis, sickle cell anemia, osteoarthritis, traumatic arthritis, osteoporosis, avascular necrosis, collagen disease, severe joint destruction secondary to trauma or other conditions and revision of previous arthroplasty.

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211163

Device Name
Bone Cement Genta

Indications for Use *(Describe)*
Bone Cement Genta are intended for the fixation of prosthesis to living bone 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.

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 OF SAFETY AND EFFECTIVENESS

1 GENERAL INFORMATION

1.1 Submitter and Owner of the 510(k)

Tecres S.p.A.
Via Andrea Doria, 6
37066 Sommacampagna, Verona
Italy

1.2 Official Correspondent

Christine L. Brauer, PhD
Regulatory Affairs Consultant
7 Trail House Court
Rockville, MD 20850

Telephone: (301) 545-1990
Email: chris.brauer@comcast.net

1.3 Devices Subject of this 510(k)

Bone Cement Genta – Low and High Viscosity
Bone Cement – Low and High Viscosity

1.4 Date of Preparation

09 January 2023

2 NAME OF THE DEVICE AND CLASSIFICATION INFORMATION

This traditional 510(k) has been submitted for the following devices.

- Bone Cement Genta – Low and High Viscosity
- Bone Cement – Low and High Viscosity

2.1 Trade/Proprietary Name

As of the date of this application, the Sponsor has not yet developed a trade name for the new bone cements for the US market.

2.2 Common/Usual Name

PMMA bone cement for orthopedics and PMMA bone cement with antibiotics for orthopedics

2.3 Classification Information

Bone Cement Genta

Classification Name:	Polymethylmethacrylate (PMMA) Bone Cement
Classification Regulation:	21 CFR § 888.3027
Regulatory Class:	Class II
Product Code(s):	LOD – Bone Cement MBB – Bone Cement, Antibiotics
Panel:	Orthopedic

Bone Cement

Classification Name:	Polymethylmethacrylate (PMMA) Bone Cement
Classification Regulation:	21 CFR § 888.3027
Regulatory Class:	Class II
Product Code:	LOD – Bone Cement
Panel:	Orthopedic

3 PREDICATE DEVICES

The predicate devices are as follows:

Bone Cement Genta:
Tecres S.p.A. NP Cement Genta HV, which was cleared originally through 510(k) application K143100.

Bone Cement:
For purposes of the substantial equivalence comparison, the following primary predicate device was selected:

- Tecres S.p.A. NP Cement HV, which was cleared through 510(k) application K143134.

A second predicate bone cement identified below was utilized as for a comparison for the indication for use statement:

- Tecres S.p.A. Cemex Bone Cement, which was through 510(k) application K021715.

4 DEVICE DESCRIPTION

Bone Cement Genta
The Bone Cement Genta are PMMA, radiopaque bone cements, containing gentamicin designed for the fixation of prosthesis to the living bone. The devices are a traditional bone cement product. The liquid is contained in a vial and the powder in a sachet; these components are packaged in unitary blister with Tyvek lid, which is placed in an aluminum bag. The components are manually mixed immediately prior to use.

The devices are sold disposable and sterile. The Bone Cement Genta are available in a low and high viscosity version.

Bone Cement
The Bone Cement are PMMA, radiopaque bone cements designed for the fixation of prosthesis to the living bone. The devices are a traditional bone cement product. The liquid is contained in a vial and the powder in a sachet; these components are packaged in unitary blister with Tyvek lid, which is placed in an aluminum bag. The components are manually mixed immediately prior to use.

The devices are sold disposable and sterile. The Bone Cement are available in a low and high viscosity version.

5 INDICATIONS FOR USE

Bone Cement Genta
Bone Cement Genta are intended for the fixation of prosthesis to living bone in the second stage of a two-stage revision for total joint arthroplasty after the initial infection has been cleared.

Bone Cement
Bone Cement LV and HV are indicated for the fixation of joint prostheses to living bone in orthopedic musculoskeletal surgical procedures for rheumatoid arthritis, sickle cell anemia, osteoarthritis, traumatic arthritis, osteoporosis, avascular necrosis, collagen disease, severe joint destruction secondary to trauma or other conditions and revision of previous arthroplasty.

6 COMPARISON OF THE INTENDED USE WITH THE PREDICATE DEVICE

Bone Cement Genta

The Bone Cement Genta has the same indication for use statement as the predicate device other than the product name. Thus, the Bone Cement Genta and the predicate device have the same intended use, as shown in Table 1.

Table 1: Comparison of the Indication Statement with the Predicate Device for Bone Cement Genta

Device	Indication for Use
Tecres Bone Cement Genta	Bone Cement Genta are intended for the fixation of prosthesis to living bone in the second stage of a two-stage revision for total joint arthroplasty after the initial infection has been cleared.
Tecres NP Cement Genta HV (K143100)	NP Cement Genta HV is intended for the fixation of prosthesis to living bone in the second stage of a two-stage revision for total joint arthroplasty after the initial infection has been cleared.

Bone Cement

Bone Cement LV and HV and the primary predicate device are intended to be used for the fixation of artificial joint prostheses to the host living bone. Thus, the devices provide the same primary function providing a proper fixation of the components of an artificial joint to the host bone and share the same intended use. There are, however, differences in the indication for use statement between the Bone Cement LV and HV and the predicate device. The indication for use statement for the Bone Cement LV and HV includes descriptive information regarding the underlying pathological conditions that often lead to the use of an artificial joint prosthesis in patients, which is not present in the primary predicate device. The same type of information is provided in the other cited predicate device, the Tecres Cemex Bone Cement, cleared through 510(k) application K021715. Importantly, the intended use of Bone Cement LV and HV remains the same as both predicate devices; all products share the same function, same mode of action, same target patient population and surgical procedures, same users, and same tissue contact (see Table 2).

Table 2: Comparison of the Indication Statement with the Predicate Devices for Bone Cement

Device	Indication for Use Statement
Tecres Bone Cement LV and HV	Bone Cement LV and HV are indicated **for the fixation of joint prostheses to living bone** in orthopedic musculoskeletal surgical procedures for rheumatoid arthritis, sickle cell anemia, osteoarthritis, traumatic arthritis, osteoporosis, avascular necrosis, collagen disease, severe joint destruction secondary to trauma or other conditions, and revision of previous arthroplasty.
NP Cement HV (K143134)	NP Cements are intended to be used **for the fixation of artificial joint prostheses to** the host **bone**.
Cemex Bone Cement (K021715)	CEMEX bone cement is indicated **for the fixation of prostheses to bone** in orthopaedic musculoskeletal procedures for osteoarthritis, rheumatoid arthritis, osteonecrosis, ankylosing spondylitis, tramatic arthritis, congenital deformities, avascular necrosis, post-traumatic degenerative problems of the joint, sickle cell anemia, osteoporosis, collagen disease and for the revision of previous arthroplasty procedures.

7 COMPARISON OF THE TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Bone Cement Genta

The Bone Cement Genta shares many of the same technological characteristics compared to the predicate NP Cement Genta HV, including important considerations such as the same materials, mechanical and chemical-physical performances.

There are, however, some differences in the formulation, packaging and method of sterilization of the powder component. These comparisons are summarized in Table 3.

Table 3: Comparison of the Technological Characteristics with the Predicate Device

Characteristics	**Tecres Bone Cement Genta**	**Tecres NP Cement Genta HV**	**Comparison**
Main Components	Polymethylmethacrylate (PMMA) Methylmethacrylate (MMA) Gentamicin Sulphate Barium Sulphate	Polymethylmethacrylate (PMMA) Methylmethacrylate (MMA) Gentamicin Sulphate Barium Sulphate	Same
Other Components	Benzoyl peroxide N,N-Dimethyl-p-toluidine Hydroquinone	Benzoyl peroxide N,N-Dimethyl-p-toluidine Hydroquinone	Same
Coloring agents	None	Pigments	Different
Mixing/Application	Manual	Manual	Same
Powder Sterilization Method	Ethylene Oxide	Gamma-ray irradiation	Different
Sterility Assurance Level (SAL) – Powder	10^{-6}	10^{-6}	Same
Liquid Sterilization Method	Filtration	Filtration	Same
SAL – Liquid	10^{-3}	10^{-3}	Same
Shelf Life	5 years	5 years	Same

Bone Cement

Bone Cement LV and HV share many of the same technological characteristics compared to the predicate NP Cement HV, including important considerations such as the same main materials, mechanical and chemical-physical performances. However, comparing the present devices with the predicate, some slight differences are present concerning the packaging, formulation, method of sterilization of the powder component and the presence/absence of colored pigments. The comparison between the devices is summarized in Table 4.

Table 4: Summary of Technological Characteristics between the Bone Cement LV and HV and the Predicate Device, NP Cement HV

Characteristics	**Tecres S.p.A - Bone Cement LV-HV Subject Device**	**Tecres S.p.A - NP Cement HV Manual Predicate Device (K143134)**	**Comparison**
Main Components	Polymethylmethacrylate (PMMA) Methylmethacrylate (MMA) Barium Sulphate	Polymethylmethacrylate (PMMA) Methylmethacrylate (MMA) Barium Sulphate	Same
Other Components	Benzoyl peroxide N,N-Dimethyl-p-toluidine Hydroquinone	Benzoyl peroxide N,N-Dimethyl-p-toluidine Hydroquinone	Same
Color Additives	None	Pigments (FD&C Blue No.1 and FD&C Yellow No.5)	Different
Mixing/Application	Manual	Manual	Same
Powder Sterilization Method	Ethylene Oxide	Gamma-ray irradiation (manual version)	Different
Single-use device	Yes	Yes	Same
Provided Sterile	Yes	Yes	Same
Sterility Assurance Level (SAL) – Powder	10^{-6}	10^{-6}	Same
Sterility Assurance Level (SAL)-Liquid	10^{-3}	10^{-3}	Same
Shelf Life	5 years	5 years	Same

8 PERFORMANCE DATA

This 510(k) submission 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: Polymethylmethacrylate (PMMA) Bone Cement; Guidance for Industry and FDA" dated July 17, 2002. The following is a summary of the performance data.

Sterilization and Shelf Life: The devices are sterilized using standard methods and the sterilization cycles have been validated following international standards. The shelf life of the devices has been established in stability studies.

Non-clinical testing: Necessary bacterial endotoxin testing has been performed.
LAL testing has been completed and the device meets the proposed limits (<0.5 EU/g).

Biocompatibility: Biocompatibility evaluation has been performed to show the device materials are safe, biocompatible and suitable for their intended use. Both ISO 10993 and

FDA Guidance "Use of International Standard ISO 10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing" have been taken into account to evaluate the biocompatibility of the device materials. The following biocompatibility studies were conducted: cytotoxicity, sensitization, intracutaneous reactivity, systemic toxicity (acute), material-mediated pyrogenicity, genotoxicity – Ames test, genotoxicity – mouse lymphoma test, implantation for 4 and 13 weeks, and chemical characterization.

Performance Testing (Chemical, Material and Mechanical): 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 (e.g., dough time, setting time)
- Chemical composition (e.g., residuals, molecular weight and polymer structure, glass transition temperature)
- Thermal properties (e.g., polymerization temperature)
- Mechanical properties (e.g., modulus and flexural properties, static compression and bending, fatigue testing, fracture toughness and viscoelasticity)

The performance data demonstrate that the new devices are substantially equivalent to the predicate devices, and meet the requirements of the Special Controls Guidance Document "*FDA Class II Special Controls Guidance Document: Polymethylmethacrylate (PMMA) Bone Cement; Guidance for Industry and FDA*" dated July 17, 2002.