April 18, 2022

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

Re: K220131
Trade/Device Name: KYPHON™ VuE™ Bone Cement
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: Class II
Product Code: NDN
Dated: January 14, 2022
Received: January 18, 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,

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)*
K220131

Device Name
KYPHON™ VuE™ Bone Cement

Indications for Use *(Describe)*
The KYPHON™ VuE™ Bone Cement is indicated for the treatment of pathological fractures of the vertebral body due to osteoporosis, cancer, or benign lesions using a cementoplasty (i.e. kyphoplasty or vertebroplasty) procedure. It is also indicated for the fixation of pathological fractures of the sacral vertebral body or ala using sacral vertebroplasty or sacroplasty. Cancer includes multiple myeloma and metastatic lesions, including those arising from breast or lung cancer, or lymphoma. Benign lesions include hemangioma and giant cell tumor. Pathological fracture may include a symptomatic microfracture (as documented by appropriate imaging and/or presence of a lytic lesion) without obvious loss of vertebral body height.

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

1 GENERAL INFORMATION

1.1 Submitter and Owner of the 510(k)

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

1.2 Official Correspondent

Christine L. Brauer, PhD
Regulatory Affairs Consultant
7 Trail House Court
Rockville, Maryland 20850
Telephone: (301) 545-1990
E-mail: chris.brauer@comcast.net

1.3 Devices Subject of this 510(k)

KYPHON™ VuE™ Bone Cement

1.4 Date of Preparation

March 16, 2022

1.5 510(k) Number

K220131

2 NAME OF THE DEVICE AND CLASSIFICATION INFORMATION

2.1 Trade/Proprietary Name

KYPHON™ VuE™ Bone Cement

2.2 Common/Usual Name

Acrylic resin for vertebroplasty/kyphoplasty

2.3 Classification Information

Classification Name:	Polymethylmethacrylate (PMMA) bone cement
Classification Regulation:	21 CFR 888.3027
Class:	II
Product Code(s):	NDN – Cement, Bone, Vertebroplasty

Panel:	Orthopaedic

3 PREDICATE DEVICE

The predicate devices are identified as follows:

- KYPHON® Xpede™ Bone Cement which was cleared originally through 510(k) application K102397 and subsequently cleared in K151227, K163032, K171938 and K191148.
- Spineplex™ Bone Cement by Stryker which was originally cleared through 510(k) notification K032945.

4 DEVICE DESCRIPTION

KYPHON™ VuE™ Bone Cement is a polymethylmethacrylate (PMMA) acrylic resin intended for use for vertebroplasty or kyphoplasty procedures, and sacroplasty procedures.

KYPHON™ VuE™ Bone Cement is a modification of the KYPHON® Xpede™ Bone Cement. Like the predicate, KYPHON™ VuE™ Bone Cement contains approximately 30% barium sulfate. However, KYPHON™ VuE™ Bone Cement contains barium sulfate in two forms (powder and granules) whereas the predicate has only the powder form of barium sulfate. The larger radio-opaque granules of barium sulfate increase visualization of the acrylic resin during delivery using fluoroscopy.

KYPHON™ VuE™ Bone Cement is provided sterile in two components: 20 grams of powder and 9 grams of liquid. The powder contains methylmethacrylate-styrene copolymer, barium sulfate and benzoyl peroxide. The liquid contains methylmethacrylate (monomer), hydroquinone and N,N-dimethyl-p-toluidine. The components are manually mixed immediately prior to use.

5 INDICATIONS FOR USE

Below is the indication for use.

The KYPHON™ VuE™ Bone Cement is indicated for the treatment of pathological fractures of the vertebral body due to osteoporosis, cancer, or benign lesions using a cementoplasty (i.e. kyphoplasty or vertebroplasty) procedure. It is also indicated for the fixation of pathological fractures of the sacral vertebral body or ala using sacral vertebroplasty or sacroplasty. Cancer includes multiple myeloma and metastatic lesions, including those arising from breast or lung cancer, or lymphoma. Benign lesions include hemangioma and giant cell tumor. Pathological fracture may include a symptomatic microfracture (as documented by appropriate imaging and/or presence of a lytic lesion) without obvious loss of vertebral body height.

6 COMPARISON OF THE INTENDED USE WITH THE PREDICATE DEVICE

The KYPHON™ VuE™ Bone Cement and the predicate devices, the KYPHON® Xpede™ Bone Cement and the Spineplex™ Bone Cement, are intended to be used in the same surgical procedure (kyphoplasty, vertebroplasty or sacroplasty procedure) in the same target patient population and have the same primary function of treatment of pathological fractures of the vertebral body. Thus, the KYPHON™ VuE™ Bone Cement has the same intended use as the predicate devices.

7 COMPARISON OF THE TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

KYPHON™ VuE™ Bone Cement shares many of the same technological characteristics compared to the predicate KYPHON® Xpede™ Bone Cement (see Table 1) and to the predicate Spineplex™ Bone Cement (see Table 2).

Table 1: Summary of Technological Characteristics between the KYPHON VuE™ Bone Cement and the Predicate Device, the KYPHON® Xpede™ Bone Cement

Characteristics	KYPHON™ VuE™ Bone Cement (Subject Device)	KYPHON® Xpede™ Bone Cement (Predicate Device, K102397, K151227, K163032, K171938 and K191148)	Comparison
Main Components	Polymethylmethacrylate (PMMA) Methylmethacrylate (MMA)	Polymethylmethacrylate (PMMA) Methylmethacrylate (MMA)	Same
	Barium Sulfate (powder and granules)	Barium Sulfate (powder only)	Different
Other Significant Components	Benzoyl peroxide N,N-Dimethyl-p-toluidine Hydroquinone	Benzoyl peroxide N,N-Dimethyl-p-toluidine Hydroquinone	Same
Mixing/Application	Manual	Manual	Same
Powder Sterilization Method	Gamma-ray irradiation	Gamma-ray irradiation	Same
Sterility Assurance Level (SAL) – Powder	10^{-6}	10^{-6}	Same
Liquid Sterilization Method	Filtration	Filtration	Same
SAL – Liquid	10^{-3}	10^{-3}	Same

Table 2: Summary of Technological Characteristics between the KYPHON™ VuE™ Bone Cement and the Predicate Device, the Spineplex™ Bone Cement

Characteristics	KYPHON™ VuE™ Bone Cement (Subject Device)	Spineplex Bone Cement (Predicate Device, K032945)	Comparison
Main Components	Polymethylmethacrylate (PMMA) Methylmethacrylate (MMA)	Polymethylmethacrylate (PMMA) Methylmethacrylate (MMA)	Same
	Barium Sulfate (powder and granules)	Barium Sulfate (powder only)	Different
Other Significant Components	Benzoyl peroxide N,N-Dimethyl-p-toluidine Hydroquinone	Benzoyl peroxide N,N-Dimethyl-p-toluidine Hydroquinone	Same
Mixing/Application	Manual	Manual	Same
Powder Sterilization Method	Gamma-ray irradiation	Irradiation	Same
Sterility Assurance Level (SAL) – Powder	10^{-6}	10^{-6}	Same
Liquid Sterilization Method	Filtration	Filtration	Same
SAL – Liquid	10^{-3}	10^{-3}	Same

8 PERFORMANCE DATA

This 510(k) notification provided performance data to establish the substantial equivalence of the KYPHON™ VuE™ Bone Cement to the predicate device. 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 device is sterilized using standard methods and the sterilization cycles have been validated following international standards. The shelf life of 2 years has been established in stability studies in that evaluated both device functionality and sterility. Bacterial endotoxin testing was performed using the LAL test (gel clot) method, following the current edition of the European Pharmacopoeia (EP) Standard 2.6.14. Bacterial Endotoxins and met the limits (<20 EU/device). The analytical procedures described in the official pharmacopoeial texts, European Pharmacopoeia (Ph. Eur.): 2.6.14. Bacterial Endotoxins, Japanese Pharmacopoeia (JP): 4.01 Bacterial Endotoxins Test, and United States Pharmacopeia (USP) General Chapter Bacterial Endotoxins Test, can be used as interchangeable in the ICH regions (Guidance for Industry Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions Annex 14 Bacterial Endotoxins Test General Chapter, October 2013).

Biocompatibility: Biocompatibility evaluation has been performed to show the device materials are safe, biocompatible, and suitable for their intended use. FDA Guidance "Use of International Standard ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" was taken into account to evaluate the biocompatibility of the device materials and the following biocompatibility studies were completed.

Biocompatibility Test	**Test Method**	**Results**
Cytotoxicity	ISO 10993-5	Not cytotoxic
Sensitization	ISO 10993-10	Not sensitizing
Intracutaneous reactivity	ISO 10993-10	No signs of erythema, eschar or edema
Systemic toxicity (acute)	ISO 10993-11	Non-toxic
Material-mediated pyrogenicity	USP 42 <151> ISO 10993-11	Absence of pyrogens
Genotoxicity (Ames test)	ISO 10993-3	Non-mutagenic
Genotoxicity (Mouse Lymphoma)	ISO 10993-3 ISO/TR 10993-33	Non-mutagenic
Implantation 13W	ISO 10993-6	No local and systemic effects-

Performance Testing: Performance testing was performed to characterize the bone cement 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)
- Sacroplasty testing (extravasation rate)

Results show comparable performances to the predicate devices and are in compliance with ASTM F451-16, ISO 5833:2002, ISO 527:1/2, ASTM F2118-14, ASTM D2990-17, ASTM D732-17 and ASTM E399-20.

The performance data demonstrate that the new devices are substantially equivalent to the predicate device and meet the requirements of the Special Controls Guidance document.