April 11, 2025

XELITE BIOMED LTD.
Mandy Lin
Regulatory Affairs Specialist
2F., No. 9, Aly. 2, Siwei Ln., Zhongzheng Rd., Xindian Dist., New Taipei City 231,
Taiwan (R.O.C.)
New Taipei City, 231022
Taiwan

Re: K243537
Trade/Device Name: XeliteMed VertehighFix High Viscosity Spinal Bone Cement System
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) Bone Cement
Regulatory Class: Class II
Product Code: NDN
Dated: November 15, 2024
Received: March 14, 2025

Dear Mandy Lin:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Robert M. Stefani -S

Digitally signed by Robert M. Stefani -S
Date: 2025.04.11 15:20:49 -04'00'

For: Jesse Muir, 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243537

Device Name

XeliteMed VertehighFix High Viscosity Spinal Bone Cement System

Indications for Use *(Describe)*

The XeliteMed VertehighFix High Viscosity Spinal Bone Cement System is intended for delivery of the XeliteMed VertehighFix High Viscosity Spinal Bone Cement, which is indicated for the treatment of pathological fracture of the vertebral body using a vertebroplasty or kyphoplasty procedure. Painful vertebral compression fractures may be caused by osteoporosis, benign tumors (e.g., hemangioma), or malignancy (e.g., metastatic cancer, myeloma).

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.

510(k) SUMMARY

1. Submission Information

Submitter: XELITE BIOMED LTD.
2F., No. 9, Aly. 2, Siwei Ln., Zhongzheng Rd., Xindian Dist., New Taipei City 231, Taiwan (R.O.C.) New Taipei City 231022 Taiwan

Submitter contact: Mr. Wei Chun Chang
Tel: +886-912111529
E-mail: raychang@xelitemd.com

Prepared date: 2025-03-12

2. Device Name and Classification

Product Name:	XeliteMed VertehighFix High Viscosity Spinal Bone Cement System
Classification Name:	Cement, Bone, Vertebroplasty
Common or Usual Name:	Polymethylmethacrylate (PMMA) bone cement
Regulation Number:	888.3027
Product Code:	NDN

3. Predicate Device(s)

Product Name:	XeliteMed VertehighFix High Viscosity Spinal Bone Cement (HSA0125/HSA0200/HSA0250) (K241775)
Common or Usual Name:	Polymethylmethacrylate (PMMA) bone cement
Regulation Number:	888.3027
Product Code:	NDN

4. Device Description

XeliteMed VertehighFix High Viscosity Spinal Bone Cement System is divided into two parts, bone cement and a delivery system.

Bone cement is provided as a two-component system. The powder component consists of a PMMA-styrene copolymer with barium sulphate as a radiopacifier and benzoyl peroxide as an initiator. The liquid component consists of methyl methacrylate monomer with the addition of hydroquinone as a stabilizer and N,N-dimethyl-p-toluidine as promoter. The powder and liquid components are mixed prior to use.

The delivery system consists of a bone cement mixing device and a hydraulic pump. The Bone Cement Mixing Device can mix and stir the powder and liquid and

transfer it to the injection barrel. Then, the bone cement is extruded and injected into the vertebral body by the hydraulic pump.

5. Indications for Use

The XeliteMed VertehighFix High Viscosity Spinal Bone Cement System is intended for delivery of the XeliteMed VertehighFix High Viscosity Spinal Bone Cement, which is indicated for the treatment of pathological fracture of the vertebral body using a vertebroplasty or kyphoplasty procedure. Painful vertebral compression fractures may be caused by osteoporosis, benign tumors (e.g., hemangioma), or malignancy (e.g., metastatic cancer, myeloma).

6. Comparison to the Predicate Device

The subject device maintains the design characteristics of the predicate device. Its indications for use and materials remain consistent with the predicate device. The only difference is the subject device is provided with an additional Class I hand-operated delivery system.

7. Performance Data

All the pre-clinical testing conducted to support the previous 510(k) clearances are applicable to the subject device.

The following non-clinical tests were performed on the delivery system.

Sterilization and Shelf Life: The Sterilization complies with ISO 11137. Product shelf-life testing was evaluated to ensure the labeled shelf life.

Biocompatibility: Biocompatibility evaluation has been performed to show the device materials are safe, biocompatible, and suitable for their intended use. The following biocompatibility studies were completed.

- Cytotoxicity
- Sensitization
- Intracutaneous Reactivity
- Systemic Toxicity (acute)
- Material-mediated Pyrogenicity

8. Conclusion

Evaluation of the subject device's intended use and technological characteristics

demonstrates substantial equivalence with the predicate device. Test data supports the shelf life and biocompatibility of the delivery system.