January 27, 2026

Xelite Biomed , Ltd.
Wei Chun Chang
RA Manager
2F., No.9, Aly. 2, Siwei Ln., Zhongzheng Rd., Xindian Dist.
New Taipei City, 231
Taiwan

Re: K251896
Trade/Device Name: XeliteMed SuperM-Fix Spinal Bone Cement
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: Class II
Product Code: NDN
Dated: June 20, 2025
Received: January 2, 2026

Dear Mr. Chang:

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,

JESSE MUIR -S

Digitally signed by JESSE MUIR -S
Date: 2026.01.28 15:09:58 -05'00'

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K251896

Please provide the device trade name(s).

XeliteMed SuperM-Fix Spinal Bone Cement

Please provide your Indications for Use below.

XeliteMed SuperM-Fix Spinal Bone Cement 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).

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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: January 25, 2026

2. Device Name and Classification

Product Name:	XeliteMed SuperM-Fix Spinal Bone Cement
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 (K241775)
Common or Usual Name:	Polymethylmethacrylate (PMMA) bone cement
Regulation Number:	888.3027
Product Code:	NDN

4. Device Description

XeliteMed SuperM-Fix Spinal Bone Cement is provided as a two component system. The powder component consists of a PMMA-styrene copolymer with barium sulphate and hydroxyapatite as radiopacifiers 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.

5. Indications for Use

XeliteMed SuperM-Fix Spinal Bone Cement 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

Items	Subject Device	Predicate Device	Comparison
Device Name	XeliteMed SuperM-Fix Spinal Bone Cement	XeliteMed VertehighFix High Viscosity Spinal Bone Cement	
K. number	K251896	K241775	/
Regulation Number	21 CFR 888.3027	21 CFR 888.3027	Identical
Product code	NDN	NDN	Identical
Indications for Use	XeliteMed SuperM-Fix Spinal Bone Cement 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).	XeliteMed VertehighFix High Viscosity Spinal Bone Cement 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).	Identical
Main Components	Polymethylmethacrylate (PMMA) Methylmethacrylate (MMA)	Polymethylmethacrylate (PMMA) Methylmethacrylate (MMA)	Identical
	Barium sulphate Hydroxyapatite	Barium sulphate	Different
Other Significant Components	Benzoyl peroxide N,N-Dimethyl-p-toluidine Hydroquinone	Benzoyl peroxide N,N-Dimethyl-p-toluidine Hydroquinone	Identical
Mixing/Application	Manual	Manual	Identical

Items	Subject Device	Predicate Device	Comparison
Device Name	XeliteMed SuperM-Fix Spinal Bone Cement	XeliteMed VertehighFix High Viscosity Spinal Bone Cement	
Powder Sterilization Method	EtO gas	EtO gas	Identical
Sterility Assurance Level (SAL) – Powder	10^{-6}	10^{-6}	Identical
Liquid Sterilization Method	Filtration	Filtration	Identical
SAL – Liquid	10^{-3}	10^{-3}	Identical
Biocompatibility	Biocompatible	Biocompatible	Identical
Performance	Compliance with Special Controls Guidance document	Compliance with Special Controls Guidance document	Identical

XeliteMed SuperM-Fix Spinal Bone Cement has the same technological characteristics as the predicate device including the fundamental scientific technology, intended use, indications for use, application method, and sterilization methods. Even though the composition is different, biocompatibility established per ISO 10993-1 and the results of performance testing are provided to support the substantial equivalence of the subject device to the predicate device.

7. Performance Data

Non-clinical tests were performed on the proposed device.

The following tests were conducted:

- Setting time and Max temperature
- Content of peroxide
- Inorganic Content
- Type of radio-opacifier
- Trace elements
- Residual monomer
- Leachables

- Molecular weights
- NMR
- Glass transition temperature
- Powder morphology
- Porosity
- Dimension change
- % Water Absorption
- Stability
- Compressive Strength & Compressive Modulus
- Bending Strength & Bending Modulus
- Tensile Strength & Tensile Modulus.
- Fatigue strength
- Package validation

Conclusion

Test data indicate that the final properties of XeliteMed SuperM-Fix Spinal Bone Cement are in compliance with applicable standards and are substantially equivalent to the predicate device.