November 3, 2025

Shanghai Lange MedTech Co., Ltd
% Chen Kevin
Official Correspondent
Shanghai Mil-Medshare Medical Technology Co., Ltd
Room 711, East Building, BHC Central Center, No. 2218 Hunan
Road, Pudong New Area
Shanghai,
China

Re: K252458
Trade/Device Name: Kyphoplasty Balloon Dilatation Catheters
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX, HXG
Dated: August 1, 2025
Received: August 5, 2025

Dear Chen Kevin:

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: 2025.11.03 11:47:03 -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.	

Please provide the device trade name(s).

Kyphoplasty Balloon Dilatation Catheters

Please provide your Indications for Use below.

Kyphoplasty Balloon Dilatation Catheters are intended to be used for the reduction and fixation of fractures and/or creation of a void in cancellous bone in the spine during balloon kyphoplasty (for use with cleared spinal polymethylmethacrylate (PMMA) bone cements).

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
K252458

I Submitter

Device submitter: Shanghai Lange MedTech Co., Ltd.
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Date: Oct 31, 2025

II Device

Trade Name of Device: Kyphoplasty Balloon Dilatation Catheters
Common Name: Inflatable BonSe Tamp
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: II
Product code: HRX, HXG
Review Panel: Orthopedic

III Correspondent

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Contact person: Kevin Chen
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IV Device description

The proposed device, Kyphoplasty Balloon Dilatation Catheters are inflatable balloon catheters used in percutaneous kyphoplasty (PKP). It consists of Inner Stylet, Balloon Catheter, and polypropylene (PP) Protection tube. The radiopaque markers located at the balloon catheter tip to reflect the balloon position during positioning.

The proposed device, Kyphoplasty Balloon Dilatation Catheters are inflatable balloon catheters used in percutaneous kyphoplasty (PKP). It consists of Inner Stylet, Balloon Catheter, and polypropylene (PP) Protection tube. The device is made of PC, stainless steel,TPU, PE, Pebax and Pt/Ir.

The inner stylet is made from a stylet attached to a 6% Luer cap. The stylet enhances the stiffness of the balloon catheter to facilitate a smooth insertion of balloon catheter through the established working pathway during the percutaneous procedure. The PP Protection tube protects the balloon from damage during the production and packaging.

The balloon catheter is composed of six sections: Inflation Port, Stylet Port, Inner Tube, Outer Tube, Radiopaque Markers, Inflatable Component. The Stylet Port is used to provide a support for the Stylet. The Inflation Port provide an adapter for a balloon inflation Injector. The Inflatable Component plays a critical role in the procedure. The Inflatable Component is to restore the height of a compression-fractured vertebral body and also leave a cavity in the fractured area after the Inflatable Component deflation. The cavity is therefore to facilitate safer filling of the bone cement. The cavity in the fractured area left by the inflated balloon reduces the filling pressure of bone cement. This technology greatly reduces the risk of uncontrollable bone cement leakage and spread, and thus lowers complications and minimizes the risk of the procedure.

The radiopaque markers located at the balloon catheter tip to reflect the balloon position during positioning.

Kyphoplasty Balloon Dilatation Catheters are supplied sterilized, single-use.

Model and specifications

There are generally two types of Kyphoplasty Balloon Dilatation Catheters, one is straight type which has a straight ballon catheter tip, and the other one is curved type which has a curved shape of tip of the balloon catheter. These catheters are available in different effective length. The detailed specifications are listed in Table 1.

Table 1 Specifications of Kyphoplasty Balloon Dilatation Catheters

<table>
<tr><th>Type</th><th>Specifications</th><th>Effective length of Inflatable Component L (mm)</th><th>Diameter Of Outer Tube D1 (mm)</th><th>Bending angle A (°)</th></tr>
<tr><td rowspan="2">Straight type</td><td>S01-1610</td><td>10±2</td><td>2.0±0.5</td><td rowspan="2">/</td></tr>
<tr><td>S01-1615</td><td>15±2</td><td rowspan="2">2.4±0.5</td></tr>
<tr><td>Curved type</td><td>S01-1620</td><td>20±2</td><td>90±20</td></tr>
</table>

V Indications for use

Kyphoplasty Balloon Dilatation Catheters are intended to be used for the reduction and fixation of fractures and/or creation of a void in cancellous bone in the spine during balloon kyphoplasty (for use with cleared spinal polymethylmethacrylate (PMMA) bone cements).

VI Substantial Equivalence

The proposed Kyphoplasty Balloon Dilatation Catheters is substantially equivalent to the predicate device:

Trade name:	Kyphoplasty Balloon Catheter	
Common name:	Inflatable Bone Tamp	
Classification name:	Product Code:	Classification:
Arthroscope	HRX	Class II, 21CFR 888.1100
Tamp	HXG	Class I, 21CFR 888.4540
Premarket Notification:	K223709	
Manufacturer:	Jiangsu Changmei Medtech Co., Ltd.	

Comparison of technological characteristics with the predicate devices

Device feature	Subject Device (Kyphoplasty Balloon Dilatation Catheters)	Predicate Device K223709 (Kyphoplasty Balloon Catheter)	Comment
Product Code	HRX HXG	HRX HXG	Equivalent
Regulation No.	21 CFR 888.1100 21 CFR 888.4540	21 CFR 888.1100 21 CFR 888.4540	Equivalent
Class	Class II	Class II	Equivalent
Indication for use	Kyphoplasty Balloon Dilatation Catheters are intended to be used for the reduction and fixation of fractures and/or creation of a void in cancellous bone in the spine during balloon kyphoplasty (for use with cleared spinal polymethylmethacrylate (PMMA) bone cements).	Kyphoplasty Balloon Catheter is intended to be used for the reduction and fixation of fractures and/or creation of a void in cancellous bone in the spine during balloon kyphoplasty (for use with cleared spinal polymethymethacrylate (PMMA) bone cements).	Equivalent
Balloon Size	10.0mm,15.0mm 20.0mm	10.0mm,15.0mm 20.0mm	Equivalent
Balloon Brust Pressure	400 psi	400 psi	Equivalent
Balloon Burst Volume	≥6ml	≥6ml	Equivalent
Balloon Inflation Behavior	Balloon Diameter:18±2 mm Balloon working length: 28±3mm	Balloon Diameter:18.3±3.0 mm Balloon working length: 28.0±3.0	Different 1 see explanation below
Tensile Force Balloon	≥15 N	≥15 N	Equivalent

Balloon Repeated Inflation	The balloon must not rupture or leak within 20 inflation/deflation cycles	The balloon must not rupture or leak within 20 inflation/deflation cycles	Equivalent
Balloon Deflation Time	≤3 s	≤3 s	Equivalent
Shapes	cylindrical	Peanut, cylindrical	Different 2 see explanation below
Inflation medium	Contrast medium	Contrast medium	Equivalent
Single/double use of catheter	Single	Single	Equivalent
Sterility	Yes	Yes	Equivalent
Biocompatibility	Confirm to the requirements of ISO 10993 series standards	Confirm to the requirements of ISO 10993 series standards	Equivalent

Discussion:

Different 1-Balloon Inflation Behavior

The difference in the size does not raise additional questions for safety and effectiveness of the device. The performance test of the subject devices has been performed on the final finished device. The test results show pass the requirements.

Different 2- Shapes

The shape of predicate device has a Peanut type, and the proposed device haven't. The shape of subject device is within the scope of predicate device. Therefore, the differences on balloon shape do not raise new questions about safety and effectiveness.

Conclusion:

The subject and predicate device have the same intended use. The differences in technological characteristics between the subject and predicate devices (i.e. Balloon Inflation Behavior and shape) do not raise different questions of safety and effectiveness. The proposed device is substantially equivalent to the predicate device.

VII Summary of non-clinical testing

Performance testing
The following tests were performed in support of the substantial equivalence determination.

Test performed	Acceptance criteria
Balloon burst pressure (Constrained)	⩾400 psi
Balloon burst volume (Constrained)	⩾6 mL
Balloon Behavior (Unconstrained Balloon Compliance) Inflation	Inflated with 6 ml, the balloon diameter should be 18±2.0 mm, and the balloon working length should be 28.0±3.0 mm.
Tensile force	⩾15 N
Fatigue	There shall be no rupture or leakage after 20 times of inflation/deflation
Balloon deflation time limits	⩽3 seconds

Biocompatibility testing
In accordance with ISO 10993-1, the Kyphoplasty Balloon Dilatation Catheters is classified as: Externally Communicating Device, Intact bone/tissue, Limited Contact (< 24hours).

The following tests were performed on the final product with a surface area of 41.08cm^2 as recommended:

Cytotoxicity	ISO 10993-5:2009
Sensitization	ISO 10993-10:2021
Irritation	ISO 10993-23:2021
Acute Systemic toxicity	ISO 10993-11:2017
Pyrogenicity	USP<151>

Sterilization and shelf life testing
- The product is sterilized by EO to maintain sterility assurance level (SAL) of 10^-6.The sterilization method has been validated to ISO 11135, ISO 11138-1, ISO 11737-1 and ISO 11737-2, which has thereby determined the routine control and monitoring parameters.
  According to ISO 10993-7, the devices are belongs to limited exposure to human body tissue/bone, so the limit of residual EO should be less than 4mg ; the limit of residual ECH should be less than 9mg. The EO/ECH residue test report shows the EO residue is less than 4mg and ECH is less than 9mg.
- Transportation test per ASTM D4169
- Packaging validation per ISO 11607-1/-2

- The 3 years shelf life of the device is determined based on stability study which includes real time aging test and simulated transportation test.
- Bacterial Endotoxin Testing per USP-NF:2023 <85>

VIII Clinical testing

N/A-No clinical test were conducted for this submission.

IX Conclusion

The proposed device has the same indication for use and has similar design features and technological characteristic as the predicate device. Performance testing data demonstrates that the proposed device is safety and effectiveness as the predicated device. Accordingly, the proposed device is substantially equivalent to the predicate.