August 16, 2023

Jiangsu Changmei Medtech Co., Ltd.
% Amber Pang
Landlink Healthcare Technology (Shanghai) Co., Ltd.
Room 1308, Baohua International Plaza
555 West Guangzhong Road
Shanghai, 200072
China

Re: K223709
Trade/Device Name: Kyphoplasty Balloon Catheter
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX, HXG
Dated: July 31, 2023
Received: July 31, 2023

Dear Ms. Pang:

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,

Jesse Muir -S

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K223709

Device Name
Kyphoplasty Balloon Catheter

Indications for Use *(Describe)*
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).

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.

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510(k) summary K223709

I Submitter

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Preparation date: Aug 8, 2023

II Proposed Device

Trade Name of Device:	Kyphoplasty Balloon Catheter
Common name:	Inflatable Bone Tamp
Regulation Number:	21 CFR 888.1100
Regulatory Class:	Class II
Product code:	HRX, HXG
Review Panel	Orthopedic

III Predicate Devices

510(k) Number:	K192449
Trade name:	Joline® Kyphoplasty System Allevo
Common name:	Vertebroplasty System; Inflatable Bone Tamp
Classification:	Class II
Product Code:	HRX, NDN
Manufacturer	Joline GmbH & Co. KG

IV Device description

Kyphoplasty Balloon Catheter is an inflatable balloon catheter used in percutaneous kyphoplasty (PKP). The Balloon Catheter consists of an outer tube and core tube/rod, inflatable balloon located at the distal tip. The radiopaque markers located at the balloon tip to reflect the balloon position during positioning.
The balloon catheter is supplied sterilized, single-use.

V Indication for use

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).

VI Comparison of technological characteristics with the predicate devices

The comparison and discussion between the subject device and the predicate device is listed in Table 1 below:

Table 1 General Comparison of Kyphoplasty Balloon Catheter

Item	Proposed device	Predicate device (K192449)	Discussion
Product name	Kyphoplasty Balloon Catheter	Joline® Kyphoplasty System Allevo	same
Product Code	HRX, HXG	HRX, NDN	same
Regulation No.	21 CFR 888.1100	21 CFR 888.1100	same
Class	Class II	Class II	same
Indication for use	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).	The Joline® Kyphoplasty System Allevo 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 polymethylmethacrylate (PMMA) bone cements).	same
Balloon Size	10.0mm, 15.0mm, 20.0mm	10.0mm, 16.0mm, 22.0mm	Different[1]
Balloon Brust Pressure	400 psi	400 psi	same
Balloon Burst Volume	≥ 6 ml	≥ 6 ml	same
Balloon Inflation Behavior	Balloon Diameter: 18.3±3.0 mm. Balloon working length: 28.0±3.0	Balloon Diameter ⩽ 19 mm Balloon working length ⩽ 24mm	Different[1]
Tensile Force Balloon	≥ 15 N	≥ 15 N	same
Balloon	The balloon must not	The balloon must not burst	Different[2]

Repeated Inflation	rupture or leak within 20 inflation/deflation cycles	within 3 inflation/deflation cycles	
Balloon Deflation Time	⩽ 3 s	⩽ 3 s	same
Shapes	Peanut, cylindrical	Cylindrical	Different[3]
Inflation medium	Contrast medium	Contrast medium	Same
Single/double use of catheter	Single	Single and double	Different[4]
Sterility	Yes	Yes	same
Biocompatibility	Confirm to the requirements of ISO 10993 series standards	Confirm to the requirements of ISO 10993 series standards	Same

[1] 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.

[2] The Balloon repeated inflation in the subject device might be different from the predicate devices. The requirement of balloon with subject device must not rupture or leak within 20 inflation/deflation cycles, and predicate device is 3 cycles. Therefore, the differences on balloon repeated inflation do not raise new questions about safety and effectiveness.

[3] The shape of proposed device has peanut type, and predicate device haven't. The peanut shape Balloon Catheter have no different in shape with the cylindrical type under rated filling volume state. Therefore, the differences on balloon shape do not raise new questions about safety and effectiveness.

[4] The predicate device has single use and double use of catheter, and proposed device have single use of catheter only. The predicated device can cover proposed device. Therefore, the differences on use of catheter do not raise new questions about safety and effectiveness.

VII Non-Clinical Testing

- **Bench test:**

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

Test Performed	**Acceptance Criteria**
Balloon Burst Pressure	Balloon Burst Pressure (Constrained) ≥

	400psi
Balloon Burst Volume	Balloon Burst Volume (Constrained) ≥ 6ml
Balloon Inflation Behavior (Unconstrained Balloon Compliance)	Inflated with 6 ml, the balloon diameter should be 18.3±3.0 mm, and the balloon working length should be 28.0±3.0 mm.
Tensile Force	Tensile force ≥ 15N.
Balloon Repeated Inflation	The balloon should withstand 20 inflation/deflation cycles at rated filling volume without rupture or leak.
Balloon Deflation Time	Deflation time ≤ 3s.

- **Biocompatibility Testing:**

In accordance with ISO 10993-1, the Kyphoplasty Balloon Catheter is classified as: Externally Communicating Device, Intact bone/tissue, Limited Contact (≤ 24hours). The following biocompatibility endpoints were addressed:

- Cytotoxicity
- Sensitization
- Intracutaneous Reactivity
- Acute Systemic Toxicity
- Material-Mediated Pyrogenicity

- **Sterility, Shipping and Shelf Life:**

The sterilization method has been validated per ISO 11135: 2014 Sterilization of health-care products – Ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices. The shelf life of the Kyphoplasty Balloon Catheter is 3 years, determined based on stability studies which includes accelerated aging and simulated shipping.

Sterilization shelf-life studies were conducted in compliance with the following standards:

Item	Standard
EO and ECH residuals	ISO 10993-7:2008 Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals
Bacteria Endotoxin Limit	USP <85> Bacterial Endotoxins
Shelf-Life Evaluation	Shelf life of 3 years is validated using the FDA recognized standard ASTM F1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

- Package integrity testing, after accelerated aging, environmental conditioning and simulated transportation in accordance with ISTA-2A:2011 68kg or less partial simulation performance test procedure for individual packaged-products, was conducted on the final, packaged, and sterile devices. All packaging deemed acceptable for protection of product and sterility maintenance.

- Sterile Barrier Packaging Testing performed on the proposed device:
  - Visual Inspection in accordance with ASTM F1886 / F1886M-16
  - Seal Strength in accordance with ASTM F88/F88M-15
  - Dye Penetration in accordance with ASTM F1929-15

VIII Clinical Testing

No clinical study is included in 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 device.