August 28, 2026

Beijing Fule Science & Technology Development Co., Ltd.
Xiaoliang Chen
Manager / International Sales
#50, Mafang W. Industry Zone, Pinggu District
Beijing, 101204
China

Re: K260203
Trade/Device Name: Fule Vertebroplasty Balloon Catheter
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX, HXG
Dated: January 23, 2026
Received: January 23, 2026

Dear Xiaoliang Chen:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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: 2026.08.28 09:58:59 -04'00'

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.	K260203

Please provide the device trade name(s).

Fule Vertebroplasty Balloon Catheter

Please provide your Indications for Use below.

Vertebroplasty 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).

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) #: K260203

510(k) Summary

Prepared on: 2026-08-27

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	BEIJING FULE SCIENCE & TECHNOLOGY DEVELOPMENT CO., LTD.
Applicant Address	No.50, Mafang West Industry Zone, Pinggu District Beijing 101204 China
Applicant Contact Telephone	+8618210731904
Applicant Contact	Mr. Xiaoliang Chen
Applicant Contact Email	xiao.liang.c.fule2@gmail.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Fule Vertebroplasty Balloon Catheter
Common Name	Arthroscope
Classification Name	Arthroscope
Regulation Number	888.1100
Product Code(s)	HRX, HXG

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K223709	Kyphoplasty Balloon Catheter	HRX

Device Description Summary

21 CFR 807.92(a)(4)

The Fule Vertebroplasty Balloon Catheter System is a sterile, single-use percutaneous instrument intended to create a controlled cavity within a vertebral body and assist in the reduction of vertebral compression fractures during vertebral augmentation. The device consists of a flexible catheter shaft, an inflatable polymeric balloon at the distal end, and radiopaque markers to enable visualization under fluoroscopy.The catheter is inserted through a prepared working channel in the pedicle. Prior to use, the balloon is evacuated to create a vacuum and then inflated with contrast medium using a compatible pressure pump. Controlled balloon expansion compacts cancellous bone and forms a cavity for subsequent injection of cleared PMMA bone cement. After cavity creation, the balloon is deflated and removed; no component of the device remains implanted.The balloon catheter is available in various working lengths and balloon sizes and is designed to withstand defined inflation pressures and volumes. Key performance features include rated burst pressure, minimum burst volume, controlled compliance, repeat inflation durability, and rapid deflation to ensure safe removal. The device incorporates medical-grade polymers suitable for limited (<24 h) externally communicating bone/tissue contact as per ISO 10993. Sterilization is achieved via validated ethylene oxide processing, and the device is supplied sterile for single use only.The system interfaces with standard percutaneous access tools (needle, dilator, bone drill), a balloon inflation pressure pump with contrast medium, and legally marketed PMMA bone cement delivery systems used in vertebral augmentation procedures.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Vertebroplasty 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).

Indications for Use Comparison

21 CFR 807.92(a)(5)

The subject device has identical Indications for Use to the predicate device (K223709) and uses the same fundamental scientific technology. Differences in dimensions do not alter the intended use or raise new questions of safety or effectiveness, as supported in the predicate's comparison discussion and performance testing. Bench testing of the subject device confirms equivalent performance in all critical functions. Therefore, the device is substantially equivalent to the predicate.

Technological Comparison 21 CFR 807.92(a)(6)

The Fule Vertebroplasty Balloon Catheter System has the same technological characteristics as the predicate device cleared under K223709. Both the subject and predicate devices are sterile, single-use percutaneous balloon catheters designed for spine kyphoplasty procedures. The devices share the same overall design concept, including an outer catheter shaft, an inner core/rod, and an inflatable balloon located at the distal tip, with radiopaque markers used to visualize balloon position during fluoroscopy.The subject and predicate devices utilize identical types of materials for the catheter shaft, balloon, and core components, and both devices use contrast medium for balloon inflation. The principle of operation is the same: the balloon is inserted into the vertebral body through a working channel and inflated to restore vertebral height and create a cavity for subsequent PMMA cement injection.The energy source and actuation method are also the same, as both devices rely solely on manual pressure delivered via a compatible inflation syringe/pump; no electrical, thermal, or powered components are involved.Biocompatibility characteristics are equivalent, as the subject device uses the same category of patient-contacting materials and is evaluated under the same ISO 10993 endpoints as the predicate. Sterilization method, sterility assurance level, and sterile barrier packaging system are also consistent with those used for the predicate device.Because the subject device's design, materials, operational principle, and performance characteristics are the same as those of the predicate device, no new technological questions related to safety or effectiveness are introduced.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The submission includes comprehensive bench and non-clinical testing to support safety and performance, consistent with FDA expectations for inflatable bone tamp systems. Testing includes, but is not limited to:
*Balloon burst pressure and burst volume
*Balloon inflation behavior and dimensional compliance
*Balloon tensile strength
*Repeated inflation/deflation durability
*Balloon deflation time
All testing demonstrates that the device meets predefined acceptance criteria and performs as intended under worst-case conditions.