June 15, 2026

Beijing Fule Science & Technology Development Co., Ltd.
Xiaoliang Chen
International Sales Manager
No.50, Mafang West Industry Zone, Pinggu District
Beijing, 101204
China

Re: K253151
Trade/Device Name: Fule Interbody Fusion Cage System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX, ODP
Dated: May 15, 2026
Received: May 15, 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,

BRENT SHOWALTER -S

Brent Showalter, Ph.D.
Assistant Director
DHT6B: Division of Spinal 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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K253151

Device Name
Fule Interbody Fusion Cage Systems

Indications for Use *(Describe)*

Cervical Device

Cervical Spine (C2–T1): The FULE Interbody Fusion Cage Systems are indicated for use as intervertebral body fusion devices in skeletally mature patients with degenerative disc disease (DDD), defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies, at one level of the cervical spine with accompanying radicular symptoms. Patients should have undergone at least six weeks of non-operative treatment prior to surgery.

The implants are intended to facilitate fusion in the cervical spine (C2–T1) and are placed via an anterior cervical approach, using autogenous bone graft. When used in the cervical spine, the FULE Interbody Fusion Cage Systems are not intended for stand-alone use and must be used with supplemental fixation systems that have been cleared by FDA for use in the cervical spine, such as anterior cervical plate and screw fixation systems.

Lumbar Devices

Lumbar Spine (L2–S1): The FULE Interbody Fusion Cage Systems are indicated for use as intervertebral body fusion devices in skeletally mature patients with degenerative disc disease (DDD), defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies, at one or two contiguous levels of the lumbar spine (L2–S1). Patients should have undergone at least six months of non-operative treatment prior to surgery.

These implants are intended to facilitate fusion in the lumbar spine and are placed via an oblique lumbar interbody fusion (OLIF), posterior lumbar interbody fusion (PLIF), or transforaminal lumbar interbody fusion (TLIF) approach, using autograft or allograft bone graft. When used in the lumbar spine, the FULE Interbody Fusion Cage Systems are not intended for stand-alone use and must be used with supplemental fixation systems that have been cleared by FDA for use in the lumbar/lumbosacral spine, such as posterior pedicle screw and rod fixation systems.

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

This 510(k) Summary is submitted in accordance with the requirements of 21 CFR 807.92.

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### 1. Submitter Information

- **Submitter:** Beijing Fule Science & Technology Development Co., Ltd.
- **Address:** No. 50, Mafang West Industry Zone, Pinggu District, Beijing, 101101, China
- **Telephone:** +86-10-60999861/2
- **Fax:** +86-10-60999863
- **Contact Person:** Xiaoliang Chen
- **Date Prepared:** 15 June 2026

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### 2. Device Name

- **Trade/Proprietary Name:** Fule Interbody Fusion Cage Systems
- **Common/Usual Name:** Intervertebral body fusion device
- **Classification Name:** Intervertebral body fusion device (21 CFR 888.3080)
- **Product Code:** MAX (Lumbar), ODP (Cervical)
- **Device Class:** Class II

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### 3. Predicate Devices

The subject device claims substantial equivalence to the primary predicate device identified below. Other legally marketed devices are identified as additional predicate devices to support approach-specific configurations and indications. These additional predicate devices are not used as split predicates;

the substantial equivalence rationale is based on the same intended use as intervertebral body fusion devices and comparable technological characteristics.

| Role | 510(k) Number | Legally Marketed Device | Purpose in SE Rationale |
|---|---|---|---|
| Primary Predicate Device | K151726 | Posterior Lumbar Interbody Fusion Cage | Primary predicate to which substantial equivalence is claimed. This device was selected because it has the same general intended use as an intervertebral body fusion device and comparable technological characteristics, including PEEK body, radiographic markers, hollow graft cavity, surface features for migration resistance, and sterile single-use configuration. |
| Additional Predicate Device | K120486 | Anterior Cervical Interbody Fusion Cage | Additional predicate used to support the cervical ACIF/ACDF configuration and cervical approach-specific indications. |
| Additional Predicate Device | K100089 | T-PAL Posterior Lumbar Interbody Fusion Cage (TLIF) | Additional predicate used to support the TLIF/T-PAL posterior lumbar approach-specific configuration. |
| Additional Predicate Device | K172828 | OLIF Interbody Fusion Cage | Additional predicate used to support the OLIF lumbar approach-specific configuration. |

No separate reference device is relied upon in this 510(k) Summary for the determination of substantial equivalence.

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## 4. Device Description

The Fule Interbody Fusion Cage Systems are hollow, implantable spinal devices manufactured from Polyetheretherketone (PEEK-OPTIMA® LT1, ASTM F2026) with optional tantalum markers (ASTM F560) for radiographic visualization.

- The devices are available in multiple configurations to accommodate different surgical approaches:
    - Anterior Cervical Interbody Fusion Cage (ACIF/ACDF)
    - Posterior Lumbar Interbody Fusion Cage (PLIF)

    - T-PAL Posterior Lumbar Interbody Fusion Cage (TLIF)
    - Oblique Lumbar Interbody Fusion Cage (OLIF)
- Each implant contains a central graft cavity to permit packing with autograft or allograft bone.
- The external surfaces incorporate serrations or ridges to resist migration and enhance initial stability.
- The devices are supplied sterile, single-use only, sterilized by irradiation.

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## 5. Indications for Use

- Lumbar Spine (L2–S1):
  The FULE Interbody Fusion Cage Systems are indicated for use as intervertebral body fusion devices in skeletally mature patients with degenerative disc disease (DDD), defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies, at one or two contiguous levels of the lumbar spine (L2–S1). Patients should have undergone at least six months of non-operative treatment prior to surgery.
- These implants are intended to facilitate fusion in the lumbar spine and are placed via an oblique lumbar interbody fusion (OLIF), posterior lumbar interbody fusion (PLIF), or transforaminal lumbar interbody fusion (TLIF) approach, using autograft or allograft bone graft. When used in the lumbar spine, the FULE Interbody Fusion Cage Systems are not intended for stand-alone use and must be used with supplemental fixation systems that have been cleared by FDA for use in the lumbar/lumbosacral spine, such as posterior pedicle screw and rod fixation systems.
- Cervical Spine (C2–T1):
  The FULE Interbody Fusion Cage Systems are indicated for use as intervertebral body fusion devices in skeletally mature patients with degenerative disc disease (DDD), defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic

studies, at one level of the cervical spine with accompanying radicular symptoms. Patients should have undergone at least six weeks of non-operative treatment prior to surgery.

- The implants are intended to facilitate fusion in the cervical spine (C2–T1) and are placed via an anterior cervical approach, using autogenous bone graft. When used in the cervical spine, the FULE Interbody Fusion Cage Systems are not intended for stand-alone use and must be used with supplemental fixation systems that have been cleared by FDA for use in the cervical spine, such as anterior cervical plate and screw fixation systems.

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## 6. Technological Characteristics

The subject devices have the same technological characteristics as the predicates, including:

- Same fundamental design (hollow body, bone graft cavity, serrated/ridged surface).
- Same materials (PEEK, tantalum).
- Same principle of operation (structural support and promotion of spinal fusion).
- Supplied sterile, single-use only.

Differences are limited to cage dimensions and approach-specific designs, which do not raise new questions of safety or effectiveness.

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## 7. Performance Data

Nonclinical testing was performed in accordance with FDA-recognized consensus standards and applicable guidance:

- Mechanical Testing (ASTM F2077, ASTM F2267):
    - Static compression, static shear, static torsion

    - Dynamic fatigue (compression and torsion)
    - Subsidence testing
- Biocompatibility (ISO 10993 series):
    - Cytotoxicity, sensitization, irritation, systemic toxicity
- Sterilization & Packaging Validation:
    - Radiation sterilization validated per ISO 11137
    - Packaging validated per ISO 11607 and ASTM F88, F1929, F2096, F1886

Results demonstrate that the subject devices perform comparably to the predicate devices and meet all acceptance criteria.

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## 8. Conclusion

The Fule Interbody Fusion Cage Systems are substantially equivalent to the identified predicate devices (K120486, K151726, K100089, K172828). The subject devices have the same intended use, indications, materials, and technological characteristics as the predicates. Performance testing confirmed that any differences do not raise new questions of safety or effectiveness.