September 6, 2024

Shanghai Iatrical-Ti Technologies Co Ltd.
℅ Charles Shen
Director
Manton Business and Technology Services
37 Winding Ridge
Oakland, New Jersey 07436

Re: K232996
Trade/Device Name: Iatrical Interbody Lumbar Fusion Systems (Model ALIF, Model TLIF, Model LLIF)
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: August 28, 2024
Received: August 28, 2024

Dear Charles Shen:

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,

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K232996

Device Name

Iatrical Interbody Lumbar Fusion Systems (Model ALIF, Model TLIF, Model LLIF)

Indications for Use *(Describe)*

The Iatrical Lumbar Interbody Fusion Systems are indicated for intervertebral body fusion of the spine in skeletally mature patients. The system is designed for use with autogenous and/or allogeneic bone graft comprised of cancellous and/or cortical cancellous bone graft to facilitate fusion and supplemental internal spinal fixation systems (e.g., pedicle screw/rod systems) cleared by the FDA for use in the thoracolumbar spine. The devices are to be used in patients who have had at least six months of non-operative treatment.

The Iatrical Lumbar Interbody Fusion Systems are intended for use in interbody fusions at the thoracolumbar junction (T12-L1), and are intended for use in the lumbar spine, from L1 to S1, for the treatment of degenerative disc disease (DDD) or degenerative spondylolisthesis at one or two adjacent levels,including thoracic disc herniation (with myelopathy and/or radiculopathy with or without axial pain). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The Iatrical Lumbar Interbody Fusion Systems can be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary:

This summary of 510k safety and effectiveness information is being submitted
In accordance with the requirements of 21CFR 807.92

1.0 Submitter & Foreign Manufacture Identification

Shanghai Iatrical-Ti Technologies Co Ltd.
Building 1, Jianchuan Road 600
Minhang District, Shanghai, China 201109
Tel: (086) 18621502232

2.0 Contact Person

Charles Shen
Manton Business and Technology Services
37 Winding Ridge, Oakland, NJ 07436
Tel: 608-217-9358
Email: cyshen@aol.com

3.0 Date of Summary: September 16, 2023

4.0 Device Name:

Trade Name:	Iatrical Lumbar Interbody Fusion Systems
Common Name:	Intervertebral Body Fusion Device
Classification Name:	Intervertebral Body Fusion Device
Product Code:	MAX
Regulation Number:	Class 2
Review Panel:	Orthopedics

5.0 Predicate Device Information:

(1) K213355, "Toro-L Interbody Fusion System"

6.0 Device description:

The IatricalLumbar Interbody Fusion Systems are intervertebral body fusion systems used in the spine. The Iatrical Lumbar Interbody Fusion Systems (LLIF, TLIF, and ALIF) are comprised of various sizes and configurations to accommodate individual patient anatomy. They may be implanted bilaterally using an anterior (ALIF) approach, a lateral (LLIF) approach, or as a single device employing a transformational (TLIF) approach.

3D printing technology is used in the manufacture of Iatrical Lumbar Interbody Fusion Systems using titanium alloy. The devices have large central graft windows which can be used with autogenous bone graft and/or allogenic bone graft, composed of cancellous, cortical, and/or corticocancellous bone prior to implantation

Iatrical Lumbar Interbody Fusion Systems are available in various heights, footprints, and lordotic angles to suit the individual patient's pathology and anatomical conditions.

Iatrical Lumbar Interbody Fusion Systems are delivered in a sterile condition and can be used without any further preparations. The devices are packaged in accordance with ISO 11607.

7.0 Indications for Use:

The Iatrical Lumbar Interbody Fusion Systems are indicated for intervertebral body fusion of the spine in skeletally mature patients. The system is designed for use with autogenous and/or allogeneic bone graft comprised of cancellous and/or cortical cancellous bone graft to facilitate fusion and supplemental internal spinal fixation systems (e.g., pedicle screw/rod systems) cleared by the FDA for use in the thoracolumbar spine. The devices are to be used in patients who have had at least six months of non-operative treatment.

The Iatrical Lumbar Interbody Fusion Systems are intended for use in interbody fusions at the thoracolumbar junction (T12-L1), and are intended for use in the lumbar spine, from L1 to S1, for the treatment of degenerative disc disease (DDD) or degenerative spondylolisthesis at one or two adjacent levels, including thoracic disc herniation (with myelopathy and/or radiculopathy with or without axial pain). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The Iatrical Lumbar Interbody Fusion Systems can be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis.

8.0 Comparison to Predicate Devices

The subject devices are substantially equivalent in indications for use, technology, and design features to the following predicate devices:

(2) K213355, "Toro-L Interbody Fusion System"

9.0 Performance Data

Performance testing included:

- Static Compression per ASTM F2077
- Static Compression-Shear per ASTM F2077
- Dynamic Compression per ASTM F2077
- Dynamic Compression-Shear per ASTM F2077

- Subsidence per ASTM F2267

10.0 Conclusions

Based on the indications for use, technological characteristics, and comparison to predicate devices, the subject device has been shown to be substantially equivalent to the aforementioned predicate devices cleared by FDA for commercial distribution in the United States.