December 6, 2024

Shenzhen Dazhou Medical Technology Co., Ltd.
% Ray Chang
Regulatory Affair
Cosmos Biomed Consulting
Room 305, No.1415, Huashan Road, Changning District,
Shanghai City,
China

Re: K241073
Trade/Device Name: DZ-Tabone™ Intervertebral Body Fusion Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP, MAX
Dated: April 18, 2024
Received: April 19, 2024

Dear Ray Chang:

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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). Under section 515C(b)(1) of the Act, a new premarket notification is not required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

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.

510(k) Number *(if known)*
K241073

Device Name
DZ-Tabone Intervertebral Body Fusion Device (CIF-PTA, LIF-PTA)

Indications for Use *(Describe)*
DZ-Tabone Intervertebral Body Fusion Device can be divided into two types, CIF-PTA and LIF-PTA.

The CIF-PTA is a cervical interbody fusion device indicated for use in skeletally mature patients with degenerative disc disease (DDD) with/ without radicular symptoms at one level from C2-Tl. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six weeks of non-operative treatment. The CIF-PTA is intended for use with supplemental fixation systems and with autogenous bone graft. The CIF-PTA is implanted via an anterior approach.

The LIF-PTA is indicated for use with autogenous bone graft as an intervertebral body fusion device at one or two contiguous levels in the lumbosacral region (L2-S1) in the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. Patients with previous non-fusion spinal surgery at involved level may be treated with the device. Patients should be skeletally mature and have had six months of non-operative treatment. The LIF-PTA is implanted using a posterior approach and is intended to be used in pairs with supplemental fixation.

DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies.

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.

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510(k) SUMMARY

1. Contact Person

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The date the summary was prepared: 2024/10/29

2. Device Name and Classification

Product Name:	***DZ Tabone™ Intervertebral Body Fusion Device (CIF-PTA, LIF-PTA)***
Classification Name:	Intervertebral body fusion device
Common or Usual Name:	Intervertebral Fusion Device With Bone Graft, Lumbar Intervertebral Fusion Device With Bone Graft, Cervical
Classification Panel:	Orthopedic
Regulation Number:	21 CFR 888.3080
Device Class:	Class II
Product Code:	MAX, ODP

3. Predicate Device(s)

Predicate device 1.

Product Name:	TM Ardis® Interbody System (K123602)
Classification Name:	Intervertebral body fusion device
Common or Usual Name:	Intervertebral Fusion Device With Bone Graft, Lumbar
Classification Panel:	Orthopedic

Regulation Number:	21 CFR 888.3080
Device Class:	Class II
Product Code:	MAX

Predicate device 2.

Product Name:	Trabecular Metal™ Fusion Device (K111119)
Classification Name:	Intervertebral body fusion device
Common or Usual Name:	Intervertebral Fusion Device With Bone Graft, Cervical
Classification Panel:	Orthopedic
Regulation Number:	21 CFR 888.3080
Device Class:	Class II
Product Code:	ODP

4. Device Description

DZ-Tabone Intervertebral Body Fusion Device is a single device manufactured wholly from tantalum metallic material. It has a convex structure on the upper and lower surfaces, and a block structure as a whole. The device has a trabecular porous structure with a central bone graft window, facilitating vertebral fusion through bone ingrowth and providing stable support between vertebrae to maintain intervertebral space height.

The device intends to be used for spinal fusion surgery for patients with degenerative disc diseases, vertebral slippage, and instability of vertebrae. The surgery involves fusing one or two adjacent vertebral segments, with the option to implant in the cervical spine (C2-T1) or lumbar spine (L2-S1) vertebral gaps. It aims to restore the lost height due to vertebral lesions and is used in conjunction with an internal fixation system.

The Device is sterilized by irradiation and provided in a sterile form. These implants are intended for single use only and must not be reused under any circumstances.

5. Intended Use / Indications for Use

DZ-Tabone Intervertebral Body Fusion Device can be divided into two types, CIF-PTA and LIF-PTA.

The CIF-PTA is a cervical interbody fusion device indicated for use in skeletally mature patients with degenerative disc disease (DDD) with/ without radicular symptoms at one level from C2-Tl. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six weeks of non-operative treatment, The CIF-PTA is intended for use with supplemental fixation systems and with autogenous bone graft. The CIF-PTA is implanted via an anterior approach.

The LIF-PTA is indicated for use with autogenous bone graft as an intervertebral body fusion device at one or two contiguous levels in the lumbosacral region (L2-S1) in the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. Patients with previous non-fusion spinal surgery at involved level may be treated with the device. Patients should be skeletally mature and have had six months of non-operative treatment. The LIF-PTA is implanted via a posterior approach

DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies.

6. Summary of Technological Characteristics

DZ-Tabone Intervertebral Body Fusion Device is a single device manufactured wholly from tantalum metallic material. It has a convex structure on the upper and lower surfaces, and a block structure as a whole. The device has a trabecular porous structure with a central bone graft window, facilitating vertebral fusion through bone ingrowth and providing stable support between vertebrae to maintain intervertebral space height.

DZ-Tabone Intervertebral Body Fusion Device provided the same intended use as predicate device with the same material, and is available in two types, CIF-PTA and LIF-PTA.

7. Summary of Non-Clinical Testing to Support Substantial Equivalence

Non-clinical testing performed on the subject device includes tests for: mechanical test, biocompatibility, sterilization, and product shelf-life.

The mechanical property was verified with the standards, " ASTM F2077 Test Methods for Intervertebral Body Fusion Devices," and " ASTM F2267 Standard Test Method for Measuring Load-Induced Subsidence of Intervertebral Body Fusion Device Under Static Axial Compression". According to the test results, Intervertebral Body Fusion Device shows comparable performance with the predicate device.

Assessment of biocompatibility of DZ-Tabone Intervertebral Body Fusion Device was performed according to ISO 10993-1:2018, demonstrating acceptable biological safety profiles.

Sterilization complies with ISO 11137, Sterilization of Health Care Products – Radiation to ensure a sterility assurance level (SAL) of 10^{-6}. Product shelf-life testing was evaluated to ensure the labeled shelf life.

Bacterial endotoxin testing was performed using the limulus amebocyte lysate (LAL) method. The LAL testing met the limit acceptance criterion of ≤ 20 EU/device, based upon the recommendations for implanted devices in the FDA guidance document Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile, issued January 21, 2016 (Section V, A, 4).

8. Clinical Testing

Not applicable; determination of substantial equivalence is not based on an assessment of clinical performance data.

9. Conclusion

DZ-Tabone Intervertebral Body Fusion Device has the same intended use, similar technological characteristics, and principles of operation as the predicate device. The results of the in vitro performance characterization and biocompatibility studies show that the DZ-Tabone Intervertebral Body Fusion Device is safe with respect to predicate device and substantially equivalent to its predicate device.