August 24, 2026

DentalMaster(Xiamen)Medical Technology Co., Ltd.
Junfeng Li
Registration and Clinical Evaluation Manager
#19-2, Dingshan Middle Rd., Haicang District
Xiamen, Fujian 361027
China

Re: K254286
Trade/Device Name: Guided Bone Regeneration System
Regulation Number: 21 CFR 872.4880
Regulation Name: Intraosseous Fixation Screw Or Wire
Regulatory Class: Class II
Product Code: DZL
Dated: August 6, 2026
Received: August 6, 2026

Dear Junfeng Li:

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,

Sherrill Lathrop Blitzer

for Andrew Steen
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental 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)*
K254286

Device Name
Guided Bone Regeneration System

Indications for Use *(Describe)*
The Guided Bone Regeneration System is indicated for the fixation and stabilization of bone grafts and bone filling materials in alveolar bone defects during alveolar bone augmentation procedures.

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

1. Submitter	
Name	DentalMaster (Xiamen) Medical Technology Co., Ltd.
Address	No.19-2, Dingshan Middle Road, Haicang District, 361027, Xiamen, Fujian, PEOPLE'S REPUBLIC OF CHINA.
Phone	+86 592 6587078
Contact person	Junfeng Li
Date prepared	August 24, 2026
2. Proposed Device	
Trade/proprietary name	Guided Bone Regeneration System
Regulation Description	Intraosseous fixation screw or wire
Regulation number	21 CFR 872.4880
Product code	DZL
Regulatory class	II
Classification panel	Dental
3. Predicate Device	
Legally marketed device(s) to which equivalence is claimed	**Predicate device:** K201210 Micro Screw System **Reference device:** K161857 Salvin Tenting Screw System
Reason for 510(k) submission	New device

4. Device Description

Guided Bone Regeneration System consists of Bone Screws and Tenting Screws. The system is an intraoral implant. The implants are provided as sterile and non-sterile. The non-sterile devices must be sterilized before use. The implants are intended for single use only.

Guided Bone Regeneration System is made of titanium alloy which meets ASTM F136.

Diameters of Bone Screws are 1.0mm and 1.3mm, and the lengths are within 4-14mm. Diameter of Tenting Screws is 1.6 mm and the lengths are within 6-14mm. Surface of subject devices are treated with anodic oxidation.

5. Indication for Use

The Guided Bone Regeneration System is indicated for the fixation and stabilization of bone grafts and bone filling materials in alveolar bone defects during alveolar bone augmentation p

rocedures.

6. Comparison of Technological Characteristics with the Predicate Device

The rationale for substantial equivalence is based on consideration of the following characteristics:

Regulatory Classification: Identical to the predicate devices

Indications for Use: Substantially equivalent (SE) to the predicate devices. The indications of the subject devices are within the indications of the predicate device.

Materials: Substantially equivalent (SE) to the predicate devices

Design Features: The dimensions of the subject devices are similar to the dimensions of the predicate devices. Differences in design features have been evaluated via performance testing.

Item	Proposed Device	Predicate Device	Reference Device
Product Name	Guided Bone Regeneration System	Micro Screw System	Tenting Screw
510(k) No.	K254286	K201210	K161857
Regulation No.	872.4880	872.4880	872.4880
Classification	II	II	II
Product Code	DZL	DZL	DZL
Provided Sterile or Non-sterile	Non-sterile and sterile	Non-sterile	Non-sterile
Indications for use	The Guided Bone Regeneration System is indicated for the fixation and stabilization of bone grafts and bone filling materials in alveolar bone defects during alveolar bone augmentation procedures.	The Micro Screw System, Micro Screw System Basic are developed and manufactured to be used as non-active bone surgery implants for the treatment of bone fractures, especially for the fixation of transplanted bone blocks during the augmentation process in the oral cavity and maxillomandibular surgical field. Note: Micro Screws are not intended to remain in the body permanently. After they have fulfilled their supportive function such as is the case after healing of a transplant, or healing of a fracture, for example, they need to be removed completely.	The Salvin Tenting Screw is used to stabilize, fixate, and/or support bone grafts, bone filling materials and / or barrier membranes used for regeneration of bone in the oral cavity.

Sizes	Bone Screws: Diameter (mm): 1.0-1.3 Length(mm): 4.0-14.0 Tenting screws: Diameter (mm): 1.6 Length(mm): 6.0-14.0	Diameter (mm): 1.0 -1.2 Length(mm): 4.0-14.0	Diameter (mm): 1.5 Length(mm): 7.0-9.0
Material	Ti-6Al-4V ELI per ASTM F136	Stainless Steel Per ASTM F138	Ti-6Al-4V ELI per ASTM F136
Surface treatment	Anodic oxidation.	Metallic- colored surface, no special surface treatment	Metallic- colored surface, no special surface treatment
Sterilization methods	Steam and Irradiation sterilization	Steam sterilization	Steam sterilization

7. Non-Clinical Performance Data

7.1 Biocompatibility testing

The biocompatibility evaluation for the Guided Bone Regeneration System was conducted on a relevant test article in accordance with the FDA Guidance "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process". The standards followed by each biocompatibility test are shown in Table below.

Test items	Reference Standards
Test For In Vitro Cytotoxicity	ISO 10993-5:2009
Guinea Pig Maximization Sensitization Test	ISO 10993-10: 2021
Intracutaneous Reactivity Test	ISO10993-23: 2021
Acute Systemic Toxicity Test	ISO 10993-11:2017
Material Mediated Pyrogen Test	ISO 10993-11: 2017
Subchronic Systemic Toxicity	ISO 10993-11:2017
Bacterial Reverse Mutation Test	ISO 10993-3: 2014
In Vitro Mouse Lymphoma Assay	
Hemolysis Test-Direct Contact And Extract Methods	ISO 10993-4: 2017
Bone Implantation Test	ISO 10993-6:2016
Subcutaneous Implantation Test	ISO 10993-6:2016

7.2 Sterilization and Packaging Validation

The Guided Bone Regeneration System is provided as sterile and non-sterile.. The shelf life of the sterile device is 5 years.

Sterile devices are sterilized by gamma irradiation sterilization, which was validated per ISO 11137 and demonstrated a Sterility Assurance Level (SAL) of 10^{-6} can be ensured. The sterile barrier system is designed to ensure the Sterility Assurance Level and protect the device

during storage and transportation. Package performance verification was performed per ISO 11607, ASTM F1980, and ISTA 2A.

Non- sterile devices shall be steam sterilized before use. The steam sterilization was validated per ISO 17665.

7.3 Mechanical testing

The axial pullout strength, insertion/removal test, torsion test and self-tapping test were performed per ASTM F543-23 Standard Specification and Test Methods for Metallic Medical Bone Screws) for both models of the subject device. The performance of the subject devices was compared to the relevant predicate device and demonstrated substantially equivalent performance.

8. Clinical Data

No clinical performance data was provided to demonstrate substantial equivalence.

9. Conclusion

Guided Bone Regeneration System is compared to the predicate devices. The information provided within this premarket notification demonstrates that proposed device is determined to be substantially equivalent (SE) to the predicate device.