Techwin Co., Ltd.
℅ Kyung-hwan Kim
Representative Consultant
SMB Korea
#606, #607, 7, Boramae-ro 5ga-gil
Donjak-gu
Seoul, 07071
REPUBLIC OF KOREA

February 08, 2024

Re: K231913
Trade/Device Name: T-FIT
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous dental implant
Regulatory Class: Class II
Product Code: OAT
Dated: January 9, 2024
Received: January 9, 2024

Dear Kyung-hwan Kim:

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.

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: 06/30/2023
See PRA Statement below.

510(k) Number
K231913

Device Name
T-FIT

Indications for Use *(Describe)*
The T-FIT is designed to provide a fixed anchorage point for attaching orthodontic appliances, facilitating the orthodontic movement of teeth. It is used temporarily and removed upon completion of the orthodontic treatment for use in patients aged 12 and older. The screws are intended for single use only.

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
For
T-FIT

[Complying with 21 CFR 807.92]

I. SUBMISSION SPONSOR

TECHWIN Co., Ltd.
#401, Eungyenam-gil 40, Siheung-si, Gyeonggi-do, Republic of Korea
Office Phone: +82-31-365-5601
Email: tw_rnd@techwinkorea.com
Contact Person: Mr. Min-jae Jo, QMR

II. SUBMISSION CORRESPONDENT

SMB Korea
#606, #607, 7, Boramae-ro 5ga-gil, Donjak-gu, Seoul, 07071, Republic of Korea
Cell Phone: +82-10-2247-5579
Office Phone: +82-6241-9001
Contact: Kyung-hwan Kim, Representative Consultant, RA/QA
Email: info@smbkorea.com

III. DATE PREPARED

February 7, 2024

IV. DEVICE

Trade or Proprietary Name:	T-FIT
Common or Usual Name:	Orthodontic Anchorage Screw
Classification Name:	Endosseous dental Implant (872.3640)
Regulatory Class:	II
Product Code:	OAT
Classification Panel:	Dental

V. PREDICATE DEVICE

K161335, Dual Top Screw System for orthodontic anchor / Jeil Medical Corporation

VI. DEVICE DESCRIPTION

The T-FIT is designed to serve as a fixed anchorage point for attaching orthodontic appliances to facilitate the movement of teeth during orthodontic treatment. The system is intended for temporary use and is removed once treatment is complete. The T-FIT is available in thread diameters Ø1.4 mm, 1.6 mm, 1.8 mm, and 2.0 mm and thread lengths of 6.0 mm, 8.0 mm, 10.0 mm, 12.0 mm, and 14.0 mm.

Thread lengths of 12.0 mm and 14.0 mm are only available with Ø2.0 mm diameter models. All screws are manufactured from Ti-6Al-4V ELI titanium alloy (ASTM F 136-13). The T-FIT is provided non-sterile and is intended for single use only. Additionally, the T-FIT is designed to be used with commonly available dental surgical instruments.

VII. INDICATION FOR USE

The T-FIT is designed to provide a fixed anchorage point for attaching orthodontic appliances, facilitating the orthodontic movement of teeth. It is used temporarily and removed upon completion of the orthodontic treatment for use in patients aged 12 and older. The screws are intended for single use only.

VIII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

<Substantial Equivalence to Predicate Devices Table – T-FIT>

	Primary PREDICATE Device (K161335)	**SUBJECT Device**	**Significant Difference**
Manufacturer	**Jeil Medical Corporation**	**TECHWIN Co., Ltd.**	-
Trade Name	Dual Top Screw System	T-FIT	-
Regulation Description	Endosseous dental implant	Endosseous dental implant	Same
Regulation Number	21 CFR 872.3640	21 CFR 872.3640	Same
Product Code	OAT	OAT	Same
Class	II	II	Same
Indications for Use	The Dual Top Screw System is intended for use as a temporary anchor for orthodontic treatment for use in patients aged 12 and older.	The T-FIT is designed to provide a fixed anchorage point for attaching orthodontic appliances, facilitating the orthodontic movement of teeth. It is used temporarily and removed upon completion of the orthodontic treatment for use in patients aged 12 and older. The screws are intended for single use only.	Difference: Although the phrasing of the indication for use of the subject device differs slightly from that of the primary predicate, the fundamental indication remains the same.
Principle of Operation	Orthodontic anchorage	T-FIT is inserted into	Same
	Primary PREDICATE Device (K161335)	**SUBJECT Device**	**Significant Difference**

	screw is inserted into jaw and palatal to help the orthodontist move the correct teeth and stop the wrong teeth from moving in the wrong direction.	either jaw to help the orthodontist move the correct teeth and stop the wrong teeth from moving in the wrong direction.	
Raw material	Ti-6Al-4V ELI Titanium Alloy (ASTM F 136)	Ti-6Al-4V ELI Titanium Alloy (ASTM F 136)	Same
Form	Orthodontic Anchorage Screw	Orthodontic Anchorage Screw	Same
Head Structure	[JA]  [JF]  [JB]  [G1]  [G2]  [JK]  [JD]  [MIM]	[TA]  [TB]  [TG]  [TS] 	Difference: The head shape design of the subject device differs slightly from that of the predicate device.
	Primary PREDICATE Device (K161335)	**SUBJECT Device**	**Significant Difference**

	 [JS] 		
Thread Diameter × Length	Length: 5.0 mm to 16.0 mm Diameter: Ø1.3 mm to Ø2.5 mm	Diameter by thread length: Ø1.4 mm × 6.0 mm to 10.0 mm Ø1.6 mm × 6.0 mm to 10.0 mm Ø1.8 mm × 6.0 mm to 10.0 mm Ø2.0 mm × 6.0 mm to 14.0 mm	Difference: The diameter and length of the design of the subject device differ slightly from those of the predicate device, but they are within the range of the predicate device.
Surface Treatment	Anodized	No surface treatment	Difference: The subject device has no surface treatment. Although this is different from the predicate device, this does not impact performance as demonstrated by bench testing.
Sterilization	Non-Sterile (Steam sterilized by user) or Gamma-Sterilized	Non-Sterile (Steam sterilized by user)	Same
Single Use/Reuse	Single use Only	Single use Only	Same
Biocompatibility	Biocompatible according to ISO 10993-1	Biocompatible according to ISO 10993-1	Same
Performance Testing	ASTM F543-17	ASTM F543-17	Same

The information provided in these 510(k) submissions demonstrates that the T-FIT is substantially equivalent to the predicate devices in terms of indications for use, function, and performance related to technological characteristics. The predicate device is made of the same material as the subject device, Ti-6Al-4V ELI titanium alloy (ASTM F 136-13). The differences between the subject and predicate devices are not expected to affect the overall performance of the device.

There are slight differences in the diameter, length, and head shape of the design between the subject and predicate devices. However, the screw diameter and length range of the subject device fall within the range of the predicate devices, and the differences in head design are minor and do not introduce significant differences in design. The technological differences between the subject device and predicate device do not raise questions of safety or effectiveness, and substantial equivalence is

demonstrated through testing in accordance with ISO 19023 and ASTM F543, as described below:

	Subject device	Primary predicate (K161335)
Torsion	Ø1.4 mm × 10.0 mm	Ø1.4 mm × 10.0 mm
Torque	Ø2.0 mm × 14.0 mm	Ø2.0 mm × 10.0 mm
Pull-out	Ø1.4 mm × 6.0 mm	Ø1.4 mm × 6.00 mm

Based on the information provided above, the T-FIT is determined to be substantially equivalent (SE) to the predicate device.

IX. NONCLINICAL TEST

The following performance data were provided in support of the substantial equivalence determination.

Mechanical Testing

The following tests were conducted on the T-FIT in accordance with ISO 19023:2018, "Dentistry – Orthodontic Anchor Screws", and ASTM F543-17, "Standard Specification and Test Methods for Metallic Medical Anchor Screw", to demonstrate substantial equivalence in terms of safety and efficacy with the predicate device:

- Torsion Test
- Torque (Insertion/fracture) Test
- Pull-out Test

Biocompatibility

The biocompatibility evaluation for the T-FIT was conducted in accordance with the FDA guidance document titled "Use of International Standard ISO 10993-1, Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process" and the following standards, as recognized by the FDA:

- ISO 7405:2018, Dentistry — Evaluation of biocompatibility of medical devices used in dentistry
- ISO 10993-1:2018, Biological evaluation of medical devices — Part 1: Evaluation and testing
- ISO 10993-5:2009, Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2010, Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization
- ISO 10993-23:2021, Biological evaluation of medical devices — Part 23: Tests for irritation
- ASTM F543-17, Standard Specification and Test Methods for Metallic Medical Bone Screws

Sterilization Testing

Sterilization validation testing was conducted in accordance with the following standards: ISO 17665-1:2006, "Sterilization of Health Care Products - Moist Heat – Part 1: Requirements for the Development, Validation, and Routine Control of a Sterilization Process for Medical Devices"; ISO/TS 17665-2:2009, "Sterilization of Health Care Products – Moist Heat – Part 2: Guidance on the Application of ISO 17665-1"; and AAMI/ANSI ST79:2017, "Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities". These standards were referenced from K161335.

A non-clinical worst-case MRI review was performed to evaluate the subject device components in the MRI environment using scientific rationale and published literature (e.g., Woods, Terry O., Jana G. Delfino, and Sunder Rajan. *"Assessment of Magnetically Induced Displacement Force and Torque on Metal Alloys Used in Medical Devices." Journal of Testing and Evaluation 49.2 (2019): 783-795)*, based on the entire system including all variations and material composition. The rationale addresses recommended parameters for MR Conditional devices according to the FDA guidance "Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment", including magnetically induced displacement force and torque.

X. CLINICAL TESTS

No clinical performance data were provided to demonstrate substantial equivalence.

XI. CONCLUSIONS

The T-FIT has been compared to the predicate device with regard to substantial equivalence. The information provided in this premarket notification demonstrates that the subject device is determined to be substantially equivalent (SE) to the predicate device.