Ze Fang Technology Co., Ltd.
℅ Anita Chen
Advisor
ZhengCheng Consulting Limited Company
No.19, 335 Lane, Fu-Xi Road, Shulin District
New Taipei City, 238
TAIWAN

October 7, 2022

Re: K202163
Trade/Device Name: Mico One Orthodontic Screw
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: OAT
Dated: September 2, 2022
Received: Septemeber 14, 2022

Dear Anita 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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Andrew I. 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 (if known)
K202163

Device Name
Mico One Orthodontic Screw

Indications for Use (Describe)
The Orthodontic Screw is indicated for use as a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of teeth. It is used temporarily and is removed after orthodontic treatment has been completed. 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.

FORM FDA 3881 (6/20) PSC Publishing Services (301) 443-6740 EF

510(k) Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness information is submitted as part of the Premarket Notification in compliance with requirements of CFR Part 807, Subpart E and Section 807.92

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The assigned 510(k) Number: K202163

1.	Submitter	
	Manufacturer Mailing Address	Ze Fang Technology Co., Ltd. 1F, No. 17, Alley 81, Lane 2, Zhongxing Rd., Sec. 1, Dali Dist., Taichung City, Taiwan (R.O.C.) Establishment Registration No.:3013689189
	Contact Person	Mrs. Anita Chen/ Regulatory Adviser of Ze Fang Technology Co., Ltd.
	Phone:	+886(0) 939-855-759
	E-mail:	m9104303@gmail.com
	Date Prepared	October 7, 2022
2	Device Name	
	Proprietary Name:	Mico One Orthodontic Screw
	Common or usual name	Orthodontic screw
	Product Code	OAT
	Device	Orthodontic screw
	CFR Classification	CFR Part 872.3640
	Device Class	II
	Classification Panel	Dental
3	Primary Predicate	K142001
	Trade or proprietary or model name:	Syntec Wetali Orthodontic Mini Screws
	Manufacturer:	Syntec Scientific Corporation No.2, Kung San Road Chuan Shing Industrial Zone, Shen Kang, Chang Hua Hsien, Taiwan R.O.C
	Reference Device:	K042345
	Trade or proprietary or	LIN/LIOU ORTHODONTIC MINI ANCHOR

	model name:	SYSTEM (LOMAS)
	Manufacturer:	Mondeal Medical Systems GmbH
		Amstel 320-1 1017AP Amsterdam The Netherlands
4	Device Description:	The screws are manufactured from commercially SUS316L (stainless steel) and Ti6AL-4V (Titanium alloy). The screws are available with thread diameter are 1.5mm and 2.0 mm, and total thread lengths is 7.0mm. The minor technological modification for **Mico One Orthodontic Screw** is designed for easy insertion and removal. The design of smooth curve surface of screw head is comfortable to patient and the screws with or without a 0.7mm/0.8mm diameter hole can supply different orthodontic methods for orthodontists.
5.	Intended Use:	Mico One Orthodontic Screw is indicated for use as a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of teeth. It is used temporarily and is removed after orthodontic treatment has been completed. Screws are intended for single use only.
	Special Conditions for Use Statement(s):	For orthodontic patient only
6.	Technological Characteristics and Substantial Equivalence Comparison with Predicate:	A comparison of the device features, intended use, and other information demonstrates that the Mico One Orthodontic Screw is substantially equivalent to the predicate device as summarized in *Table 1*. The differences raise no new question of safety and effectiveness.

Table 1

510(K) Number	K202163	K142001	K042345
Device Name	Mico One Orthodontic Screw	Syntec Wetali Orthodontic Mini Screws	Lin/Liou Orthodontic Mini Anchor System (Lomas)
Manufacturer	Ze Fang Technology Co., Ltd.	Syntec Scientific Corporation	Mondeal Medical Systems GmbH
Head structure	Hexagon mushroom head, Four-corner mushroom head, Tetragonal mushroom head, Four-corner mushroom head half thread type, Four-corner headless, Hexagonal wing head, Hexagon HOOK head type, Round cross-shaped groove, Hexagonal hole type above the round head, Small hexagon mushroom head	Four-corner mushroom head, Tetragonal mushroom head, Four corner HOOK head type, Hexagon mushroom head, Small hexagonal mushroom head, Short four-cornered mushroom head	Four-corner cross-section, Four corner HOOK head type, Four-corner wing head
Body Diameter (D)	Ø 1.5mm, Ø 2.0mm	From 1.4mm to 2.0mm	From 1.5mm to 2.0mm
Length (mm)	7mm	From 5.0mm to 17.0mm	From7mm to 11mm
Material of Fixture	SUS316L (stainless steel) ASTM-F138, Ti6AL-4V ASTM-F136	SUS316L (stainless steel) , Ti6AL-4V	Ti6AL-4V

Shelf life	2 years	15 years	NA
Indication for use	Mico One Orthodontic Screw is indicated for use as a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of teeth. It is used temporarily and is removed after orthodontic treatment has been completed. Screws are intended for single use only	The screws are indicated for use as a fixed anchorage for attachment of orthodontic appliances to facilitate the orthodontic movement of teeth. They are used temporarily and are removed after orthodontic treatment has been completed. They are intended for single use only.	The Lin/Liou Orthodontic Mini Anchor System (LOMAS) is intended to provide a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of teeth. The device is used temporarily and is removed after orthodontic treatment has been completed. Screws are intended for single use only

A minor technological difference between the predicate device and subject device is one piece assembled with main device and 3 components of Mico One Orthodontic Screw. But both of us used the same technological design for ligating. Bench testing

demonstrates that Mico One Orthodontic Screw can successfully remove the tooth to maintain the position. And the diameter and length are included in the range of the predicate device. Although there is a slightly different technological design, as compared to the predicate, the performance data demonstrates the proposed device performs in a similar manner as the predicate device. Therefore, we believe Orthodontic screw is “Substantially Equivalent” to the predicate devices.

7. Performance Testing

Performance testing has been carried out to demonstrate that this device meets the performance specifications for its intend use. The following tests were performed on the device.

- ASTM F543-Standard Specification and Test Methods for Metallic Medical Bone Screws

Mico One Orthodontic Screw’s mechanical function including Shear Bond Strength, Torque Strength test and structure integrity were tested and demonstrated that the design specification from design input are fulfilled. Mechanical performance tests were also conducted to demonstrate the reliability of the device for the intended function during use.

Biocompatibility testing

The biocompatibility evaluation and testing of the Mico One Orthodontic Screw was conducted in accordance with the following standards and guidance, as recognized by the FDA:

- FDA Guidance - Use of International Standard ISO- 10993, "Biological Evaluation of Medical Devices, Part 1: Evaluation and Testing", 2020.
- ISO 10993-3,Biological evaluation of medical device-Part 3: Test for genotoxicity, carcinogenicity and reproductive toxicity.
- ISO 10993-5, Biological evaluation of medical device-Part 5: Tests for in vitro cytotoxicity.
- ISO 10993-6, Biological evaluation of medical devices -- Part 6: Tests for local effects after implantation.
- ISO 10993-10, Biological evaluation of medical device-Part 10: Tests for irritation and skin sensitization.

- ISO 10993-11, Biological evaluation of medical device-Part 11: Tests for systemic toxicity.
- ISO 10993-12, Biological evaluation of medical device-Part 12: Sample preparation and reference materials.

Sterilization Validation

Device is provided in non-Sterile but user will sterilized before use. Moist Heat sterilization validation was conducted in accordance with ISO 17665-1.

No animal studies or clinical testing have been required for these devices.

8. Conclusion

Based on the intended use and/or indications for use, technological characteristics, performance testing and comparison to the predicate device, the Mico One Orthodontic Screw is substantially equivalent.