12/19/21

MK Meditech Inc.
Sungchul Moon
Representative
Room# 511, 54, Changeop-ro, Sujeong-gu,
Seongnam-si, Gyeonggi-do 13449
KOREA, SOUTH

Re: K210559
Trade/Device Name: ATOZ Mini-Screw
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: OAT
Dated: August 2, 2021
Received: November 18, 2021

Dear Sungchul Moon:

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,

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 *(if known)*
K210559

Device Name
ATOZ Mini-Screw

Indications for Use *(Describe)*
The ATOZ Mini-Screw is intended for use as a temporary anchor for orthodontic treatment.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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

K210559

1. Submitter Information

Manufacturer: MK Meditech Inc.
Room # 511, 54, Changeop-ro, Sujeong-gu, Seongnam-si, Gyeonggi-do, 13449, Korea.

Contact Person: SungChul Moon, Ph.D.
Representative of MK Meditech Inc.
Tel+82-31-759-2885, (Fax) +82-31-759-2886
e-mail: orthofor@chol.com

Date Prepared: December 17, 2021

2. Device Information

Trade Name: ATOZ Mini-Screw

Model Number: MKS-1608, MKS-1609, MKS-1610, MKS-1611, MKS-1612, MKS-1613, MKS-1614, MKS-1615 and MKS-1616

Common Name: Orthodontic Anchor Screw

Product Code: OAT (Implant, Endosseous, Orthodontic)

Regulation Number: 21CFR 872.3640

Class: 2

3. Predicate Device Information

Predicate Device: K161335 (Dual Top Screw System)

Reference Device: K063495 (C, CT and Special Type Orthodontic Anchor Screws)

4. Description of the Device

The ATOZ Mini-Screw is a temporary screw used as a fixing point for orthodontic treatment. The screw head has a round shape and has a cross groove in the middle so that it can be inserted and removed with a dental screwdriver.

The ATOZ Mini-Screw has several models of the same design and diameter, only different lengths.
The material of The ATOZ Mini-Screw is Titanium Alloy (ASTM F136), which is widely used in dental implants, and due to the nature of the temporary screw that is removed before bone union occurs, no surface treatment is applied.

The average implantation period of the set screw is 6 months and must be used after autoclaving by the user before use. It is single-use only and may not be reused.

The screw is designed to withstand the external force sufficiently during orthodontic treatment of the screw, and its mechanical performance has been evaluated according to ISO 19023 and ASTM F543.

5. Indication for Use

The ATOZ Mini-Screw is intended for use as a temporary anchor for orthodontic treatment.

6. Technological Characteristics

The subject device has the same purpose and raw materials as the predicate device. The design of the screw differs in diameter and length and the shape of the head.

	Subject Device	Predicate Device	Reference Device
510(k) Number	K210559	K161335	K063495
Product Name	ATOZ Mini-Screw	Dual Top Screw System	The C-Type, CT Type and Special Type Orthodontic Anchor Screws
Product Code	OAT	OAT	OAT
Manufacturer	MK Meditech Inc.	Jeil Medical Corporation	Biomaterials Korea Incorporated
Indication for Use	The ATOZ Mini-Screw is intended for use as a temporary anchor for orthodontic treatment.	The Dual Top Screw System is intended for use as a temporary anchor for orthodontic treatment for use in patients aged 12 and older.	Intended for use as a temporary anchor for orthodontic treatment.
Material	Titanium Alloy (ASTM F136)	Titanium Alloy (ASTM F136)	Titanium Alloy (ASTM F136)
Surface Treatment	No surface treatment	No surface treatment	Anodized
Design	Screw - Thread Diameter: Ø 1.6mm - Thread Depth: 0.54mm - Length: 8mm~16mm	Screw - Thread Diameter: Ø 1.3~ Ø 2.5mm - Thread Depth: 0.15 ~0.55mm - Length: 5~16mm	Screw - Thread Diameter: Ø 1.2~Ø 2.0mm - Thread Depth: 0.14mm - Length: 5~12mm
Sterilization	Non-Sterile (Steam sterilized by user)	Non-Sterile (Steam sterilized by user) or Gamma- Sterilized	Non-Sterile (Steam sterilized by user)

7. Summary of Non-Clinical Data

The following bench test and biocompatibility were conducted using the ATOZ Mini-Screw, demonstrating the device as substantially equivalent to the previously cleared predicate device.

- Bench Test

The test items below to measure the mechanical strength of the ATOZ Mini-Screw were performed according to ISO 19023 and ASTM 543.

- Torque strength
- Torsional strength
- Pullout strength

- Biocompatibility

The subject device is manufactured from Titanium alloy (conforming with ASTM F136). The tests below were conducted to demonstrate biocompatibility of this device according to ISO 10993-1:2018.

- In vitro Cytotoxicity (ISO 10993-5:2009)
- Skin Sensitization (ISO 10993-10:2010)
- Oral mucosa irritation (ISO 10993-10:2010)
- Acute systemic toxicity study (ISO 1093-11:2017)
- Chemical analysis test (ISO 10993-18:2020)
- Biological Safety Assessment

- Sterilization

The subject device is provided Non-Sterile. The end user must sterilize according to the recommended parameters (121 degrees/30 minutes sterilization, 30 minutes drying) using an autoclave before use. In this sterilization parameter, the subject device meets Sterility Assurance Level of 1E-6 and has been verified according to the standards below.

- 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
- ISO 11138-1:2017, Sterilization of health care products — Biological indicators — Part 1: General requirements
- ISO 11138-3: 2017, Sterilization of health care products — Biological indicators — Part 3: Biological indicators for moist heat sterilization processes
- ISO 11737-1:2018, Sterilization of medical devices — Microbiological methods — Part 1: Determination of a population of microorganisms on products
- ISO 11737-2:2019, Sterilization of health care products — Microbiological methods — Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
- ANSI/AAMI ST79:2017, Comprehensive guide to steam sterilization and sterility assurance in health care facilities

10. Summary of Clinical Data

Clinical Data was not required to demonstrate the substantial equivalence

11. Conclusion

The ATOZ Mini-Screw and predicate device have the same indication for use, the same raw materials and the same characteristics. In addition, the substantial equivalence of the subject device was confirmed through a non-clinical testing. Therefore, the ATOZ Mini-Screw has been proven to be equivalent to a predicate device.