January 17, 2020

BIO CETEC CO., LTD.
% Dave Kim
Medical Device Regulatory Affairs
MTech Group Inc.
8310 Buffalo Speedway
Houston, Texas 77025

Re: K190871
Trade/Device Name: Bio-TackS Orthodontic Mini Implant
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: OAT
Dated: December 17, 2019
Received: December 17, 2019

Dear Dave 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 (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 Srinivas Nandkumar, Ph.D.
Director
DHT1B: Division of Dental 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190871

Device Name
Bio-TackS
Orthodontic Mini Implant

Indications for Use *(Describe)*

The Bio-TackS Orthodontic Mini Implant 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.

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K190871

510(k) Summary

This summary of 510(k) is being submitted in accordance with requirements of 21 CFR Part 807.92

Date: January 17, 2020

1. 510K Applicant / Submitter:

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Fax: +82-2-704-2877

2. Submission Contact Person

MTech Group Inc.
7707 Fannin St. Ste 200, V111, Houston, TX 77054
Mr. Dave Kim
Phone: 713-467-2607
Email: davekim@mtech-inc.net

3. Device

- Trade / Device Name : Bio-TackS Orthodontic Mini Implant
- Classification Name : Implant, Endosseous, Orthodontic
- Regulation Number : 21 CFR 872.3640
- Regulation Name : Endosseous dental implant
- Regulatory Class : II
- Product Code : OAT

4. Predicate Device

- Trade / Device Name : Orthodontic Screw
- 510(k) Number : K161197
- Regulation Number : 21 CFR 872.3640
- Regulation Name : Endosseous dental implant
- Regulatory Class : II
- Product Code : OAT

5. Description:

Fixed on jawbone the Bio-TackS Orthodontic Mini Implant is a screw-shaped product used as a fixed point for orthodontic treatment and it is applied in order to secure sufficient physical and mechanical fixing source for treatment.

6. Indications for Use

The Bio-TackS Orthodontic Mini Implant 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.

7. Substantial Equivalence Discussion:

The Bio-TackS Orthodontic mini implant is substantially equivalent to Osstem Orthodontic Screw (K161197). The following comparison table is presented to demonstrate substantial equivalence.

	Subject Device	Predicate 1	SE Analysis
510(k) Number	K190871	K161197	-
Device Name	Bio-TackS Orthodontic Mini Implant	Orthodontic Screw	-
Common Name	Orthodontic mini implant	Orthodontic mini implant	-
Manufacturer	BIOCETEC CO., LTD.	OSSTEM Implant Co., Ltd.	-
Design	**Details refer to below Table(※)**		-
Indication for Use	The Bio-TackS Orthodontic mini implant 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 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.	SE
Head Structure	Simple Head, Through Hole, Small Head, Bracket Head, Hex Head, Hex Cross, Hex Open Cross, Simple Head Hex Stopper, Small Head Hex Stopper, Through Hole Stopper	Simple Head, Through Hole, Small Head, Bracket Head	Different
Body Diameter	Ø 1.4mm, Ø 1.6mm, Ø 1.8mm	Ø1.2mm, Ø 1.4mm, Ø 1.6mm, Ø 1.8mm	SE
Length	6mm, 8mm, 10mm	6mm, 8mm, 10mm	SE
Material of Fixture	Ti-6Al-4V ELI [ASTM F136]	Ti-6Al-4V ELI [ASTM F136]	SE
Surface Treatment	Machined	Machined	SE
Sterilization	Radiation	Radiation	SE
Shelf-life	5 years	8 years	-
Target Population	Professional use only – qualified dentists. Strictly reserved to specialized and trained users.	Professional use only – qualified dentists. Strictly reserved to specialized and trained users.	SE
Principles of operation	Orthodontic screw is inserted into either jaw to help the orthodontist move the correct teeth and stop the wrong teeth from moving in the wrong direction.	Orthodontic screw is inserted into either jaw to help the orthodontist move the correct teeth and stop the wrong teeth from moving in the wrong direction.	SE
Single use	Yes	Yes	SE
Sterile Packaging	Yes	Yes	SE
Target Population	Patients in need of Dental orthodontics, maxillofacial surgery	Patients in need of Dental orthodontics, maxillofacial surgery	SE
Anatomical Site	Teeth	Teeth	SE
Location of Use	Use only by professional orthodontists	Use only by professional orthodontists	SE
Bio-compatibility	All user directly contacting materials are compliance with ISO10993 requirements.	All user directly contacting materials are compliance with ISO10993 requirements.	SE

(※) Images(Photos) of each type

No	Type	External Appearance
1	Orthodontic Screw Simple Head type	
2	Orthodontic Screw Through Hole type	
3	Orthodontic Screw Small head type	
4	Orthodontic Screw Bracket Head type	
5	Orthodontic Screw Hex Head type	
6	Orthodontic Screw Hex Cross type	

7	Orthodontic Screw Hex Open Cross type	

Diameter-Length Combinations (in mm) for the Proposed Device:

1. 1.4x6, 1.4x8
2. 1.6x6, 1.6x8, 1.6x10
3. 1.8x6, 1.8x8, 1.8x10

Bio-TackS Orthodontic Mini Implant and the predicate device (Osstem Orthodontic Screw (K161197)) have identical indication for use statements and the same intended use.

It shows equivalent specifications with the predicate devices in most of parameters.

However, there are differences in the device design characteristics (Head structure).

	Bio-TackS	Orthodontic Screw (K161197)
Body Diameter	Ø 1.4mm, Ø 1.6mm, Ø 1.8mm	Ø1.2mm, Ø 1.4mm, Ø 1.6mm, Ø 1.8mm

The different head structure for the subject device include Hex Head, Hex Cross, Hex Open Cross, Simple Head Hex Stopper, Small Head Hex Stopper, Through Hole Stopper.

8. Performance Tests (Non-clinical)

Non-clinical performance tests were performed according to the test standard, ASTM F543 Standard Specification and Test Methods for Metallic Medical Bone Screws.

The following tests for performance of the subject device have been conducted;

Sterilization and Shelf Life:

Sterilization validation was performed according to ISO 11137-1, ISO 11137-2, and ISO 11137-3 using the VDmax25 method. Shelf life of the packaging was demonstrated by accelerated aging of the product with evaluations for seal peeling (ASTM F88), dye penetration (ASTM F1929), and sterility testing.

Insertion-Removal torque test

According to the test standard (ASTM F543-07 A1), Insertion torque / removal torque testing is performed to evaluate the mechanical stability of orthodontic mini implants. The largest diameter (1.8mm) and longest (10mm) screws are tested as the worst case; BSH1810S (BioTackS), OSSH1810 (Osstem Mini Implant). With the same diameter and length, both samples demonstrated almost equivalent torque values when inserted and removed at 1440 degrees at 1 rpm. A slight difference in the results is due to the different in drill-bit design and thread design.

Rotational fracture torque strength test

According to the test standard (ASTM F543-07 A1), Rotational fracture torque testing is performed to determine the material yield strength. The smallest diameter (1.4mm) with a 10mm length; BSH1408S (BioTacks), OSSH1408 (Osstem mini implant) were tested. The tapered implant fracture occurred in the same tread section. Both implants are made from the same raw material (titanium alloy-ELI grade 23), so the material yield strengths of both products are the same.

In addition, all screw-head types, with the same diameter and length, are tested.

Axial pull-out strength testing

According to the test standard (ASTM F543-07 A1), Pull-out strength testing is performed for the effectiveness of the mechanical design of the orthodontic mini implant and its elimination. The screw samples with the shortest (6mm) and smallest diameter (1.4mm) were tested; BSH1406S (BioTackS), OSSH1406 (Osstem mini implant). The test data demonstrated similar results due to the similar pitch tread thickness of the samples.

Table 1. Description of orthodontic mini implant Used in This Study

Test	Type	Diameter	Length	Shape
Insertion-Removal torque testing	BSH1810S (BioTackS)	1.8 mm	10 mm	Taper
	OSSH1810 (Osstem)	1.8 mm	10 mm	Taper
Rotational fracture torque testing	BSH1408S (BioTackS)	1.4 mm	8 mm	Taper
	OSSH1408 (Osstem)	1.4 mm	8 mm	Taper
Axial Pull-out strength testing	BSH1406S (BioTackS)	1.4 mm	6 mm	Taper
	OSSH1406 (Osstem)	1.4 mm	6 mm	Taper

Bench Test included rotational fracture torque strength testing for all screw-head types, with the same diameter and length. The test results were similar. Differences of Head structure do not affect effectiveness or safety of the Bio-TackS Orthodontic Mini Implant and Predicate Device.

The results of the bench testing demonstrate similar performance for Bio-TackS Orthodontic Mini Implant and the predicate device.

Biocompatibility testing accordance with ISO 10993-1 has been conducted for Bio-TackS Orthodontic Mini Implant.

- Category : Implant Device for Tissue / Bone
- Contact duration: C-permanent (>30d)

Human Contact Part	**Test Item**	**Test Report Number**	**Test Standard**	**Test Result**
Tissue / Bone	Cytotoxicity	180600062 PPT-18-0028-01(E)	ISO 10993-5	Non-cytotoxic
	Acute Systemic Toxicity	180600062 PPT-18-0028-02(E)	ISO 10993-11	Non-acute systemic toxicity
	Intracutaneous (Intradermal) Reactivity	180600062 PPT-18-0028-03(E)	ISO 10993-10	None Irritation
	Local Lymph Node Assay (LLNA)	180600062 PPT-18-0028-04(E)	ISO 10993-10	Do not show any hypersensitivity

Biocompatibility testing including Cytotoxicity, Sensitization, Irritation or Intracutaneous Reactivity, Systemic Toxicity was completed according to the following standards:
ISO 10993-1:2009 Biological Evaluation of Medical Devices –Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
ISO 10993-5:2009 Biological Evaluation of Medical Devices – Part 5 Cytotoxicity
ISO 10993-10:2010 Biological Evaluation of Medical Devices Part 10: Tests for irritation and skin sensitization
ISO 10993-11:2017 Biological Evaluation of Medical Devices Part 11: Tests for systemic toxicity test

The biocompatibility test results demonstrated that there is no new concern in the cytotoxicity, acute systemic toxicity, intracutaneous reactivity, local lymph node assay (LLNA).

Subchronic Toxicity Test, Genotoxicity Test, Implantation were not conducted due to the reasons as follows;

Products with titanium materials tested according to the contents of ASTM F 136, X2. BIOCOMPATIBILITY in Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications of ASTM F136 do not have side effects on safety after a procedure.

X2. BIOCOMPATIBILITY
X2.1
The alloy composition covered by this specification has been employed successfully in human implant applications in contact with soft tissue and bone for over a decade. *Due to the well-characterized level of biological response exhibited by this alloy, it has been used as a control material in Practice F 981.*

9. SUMMARY OF CLINICAL TESTS

Clinical testing was not required to demonstrate the substantial equivalence of the Bio-TackS Orthodontic Mini Implant to its predicate device.

10. Conclusions:

Based on the information above, Bio-TackS Orthodontic Mini Implant has same indications for use and intended use. Both the subject device and the predicate / reference devices have shown similar performance results in these bench tests

In conclusion, Bio-TackS Orthodontic Mini Implant is substantially equivalent to the predicate device as described herein.