



BioMaterials Korea, Inc
Jiyea Kim
Staff
#413, #329, #331 150, Jojeong-daero, Hanam-si
Gyeonggi-do, KR 12930

August 30, 2018

Re: K173623
Trade/Device Name: Anchor plate
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: OAT
Dated: November 9, 2017
Received: November 24, 2017

Dear Jiyea 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mary S. Runner -S

For Tina Kiang, Ph.D.

Acting Director

Division of Anesthesiology,

General Hospital, Respiratory,

Infection Control, and Dental Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K173623

Device Name

Anchor plate

Indications for Use (Describe)

The subject devices are intended to be place in the mouth for use as an anchor in orthodontic 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.

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005. 510(k) SUMMARY

Date: August 30, 2018

1. Submitter:

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Fax: 720-9625413
Contact name: Kevin Walls
Email: Kevin@Reginsight.com

2. Device Name and Classification

Trade/Proprietary Name: Anchor Plate
Common Name: Endosseous Dental Implant
Regulatory Class: Class II, 872.3640
Product Code: OAT

3. Predicated Device








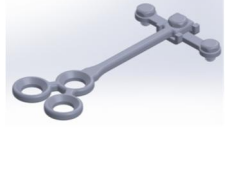




- Primary Predicate Device
BOLLARD MINIPLATE SKELETAL ANCHORAGE SYSTEM, TITA-LINK, K091051
- Reference Predicate Devices
KLS MARTIN ORTHO ANCHORAGE SYSTEM, KLS-MARTIN L.P., K040891
SYNTHES ORTHODONTIC BONE ANCHOR SYSTEM, SYNTHES(USA), K063473




4. Device Description

The anchor plates for attachment to the orthodontic device offer four types (T-Type, I-Type, Y-Type and W-Type). This plate has three portions; head, arm and body, and there are two types of head portion.

Anchor plate is developed to provide intraoral absolute anchorage for the intrusion or distalization of molars. Anchor Plate does not disturb any kind of tooth movement because they are placed outside the dentition. The anchor plate consists of pure titanium and titanium alloy, which is suitable for osseointegration and also tissue integration.

Compatibility information is summarized in the table below.

Anchor plate		Screw		
Design	Type	Design	Trade names	Model name
	T-Type		Bone Screw	OSS-T2004S OSS-T2005S OSS-T2006S
	I-Type		Bone Screw	OSS-T2004S OSS-T2005S OSS-T2006S
				
				
				
	Y-Type		Bone Screw	OSS-T2004S OSS-T2005S OSS-T2006S
	W-Type		CT Type	OAS-T1506T
			C-Type	OAS-T1507

	W-Type		CT Type	OAS-T1506T
			C-Type	OAS-T1507

5. Intended Use





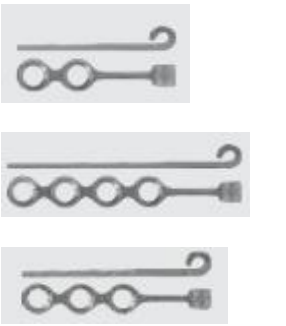
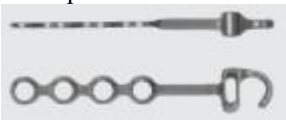
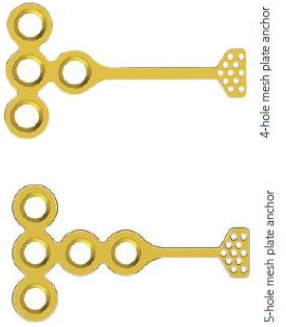
The subject devices are intended to be place in the mouth for use as an anchor in orthodontic procedures.

6. Comparison of technological characteristics with the predicate device

-	Proposed Device	Primary Predicate Device (K091051)	Reference Predicate Device I (K040891)	Reference Predicate Device II (K063473)	Discuss/Justify the differences
Trade name	Anchor Plate	BOLLARD MINIPLATE SKELETAL ANCHORAGE SYSTEM	KLS MARTIN ORTHO ANCHORAGE SYSTEM	SYNTHESES ORTHODONTIC BONE ANCHOR SYSTEM	
Common name	Endosseous dental implant	Endosseous dental implant	Bone plate	Endosseous dental implant	Same
Classification name	Endosseous implant	Endosseous implant	Endosseous implant	Endosseous implant	Same
Class	II	II	III	II	Same
Product Code	OAT	DZE	DZE	OAT	<p>There are different product codes, DZE and OAT, between proposed device and predicate devices. However, all devices consist of orthodontic anchorage system under same intended use.</p> <p>For product code as DZE, Bollard Miniplate Skeletal Anchorage System (K091051) and Ortho Anchorage System (K040891) are used as an anchor for orthodontic procedures by providing skeletal fixation which are same with T-Type, I-Type and Y-Type of proposed device.</p> <p>For product code as OAT,</p>

					The Orthodontic Bone Anchor System (K063473) are used as an anchor for orthodontic procedure by providing bone fixation which is same with W-Type of proposed device.
Device description	<p>The anchor plates for attachment to the orthodontic device offer four types (T-Type, I-Type, Y-Type and W-Type). This plate has three portions; head, arm and body, and there are two types of head portion.</p> <p>Anchor plate is developed to provide intraoral absolute anchorage for the intrusion or distalization of molars. Anchor Plate does not disturb any kind of tooth movement because they are placed outside the dentition. The anchor plate consists of pure titanium and titanium alloy, which is suitable for osseointegration and also tissue integration.</p>	<p>The Bollard Miniplate Skeletal Anchorage System was invented by Dr. Hugo DeClerck. The Bollard Miniplate Skeletal Anchorage System provides a fixed anchorage point for the attachment of orthodontic appliances to facilitate orthodontic movement of teeth. Small stationary points connected to bone inside the Mouth allow connection of wire, elastic, or other hardware. The Bollard Miniplate Skeletal Anchorage System includes Commercially Pure Titanium miniplates fixed by miniscrews to the cortical bone. After insertion by the surgeon the miniplates are completely covered by soft tissue. The miniplates and miniscrews are sold sterile and are sterilized using Gamma Radiation per ISO 11137-1.</p>	The KLS-Martin Ortho Anchorage System includes several different designs of titanium plates.	The Synthes (USA) Orthodontic Bone Anchor System is a plate and screw system designed to be implanted intraorally and used as an anchor for orthodontic procedures. The plate anchor portion of the system consists of T-shaped plate anchors which are attached to the bone via 1.55 mm cortex screws and 1.85 mm emergency screws. The plate anchors are offered in various designs for attachment to the orthodontic device. The screw anchor portion of the system consists of 1.55 mm self-drilling and self-tapping screw anchors which incorporate a non-threaded gingival collar beneath the screw head which protects the soft tissue.	Same

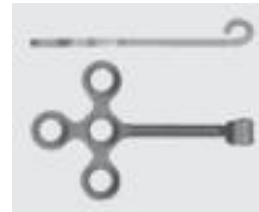
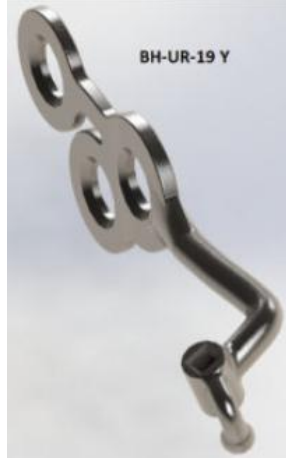
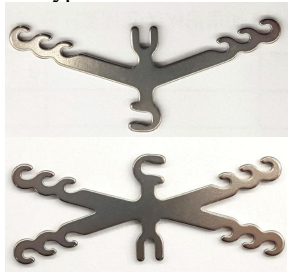
		<p>The bone anchor consists of a miniplate (M) with 2 or 3 holes, a round connecting bar (C), and a fixation unit (F) with a blocking screw (5). The miniplate is fixed to the bone by self-tapping or selfdrilling screws. The fixation unit contains 2 slots with a diameter of 0.045" (1.1mm). A square connecting wire with a maximum size of 0.032x0.032" can be inserted and tightly fixed by the blocking screw.</p> <p>The Bollard miniplates are also offered with a hook. The Bollard with hook is smaller than the original model and contains a tube with section 0.020"x0.020". The hook can affix directly to elastics or coil springs</p> <p>The subject devices are used with standard instrumentation for orthodontic surgery including pliers, punches, screwdrivers, burrs, and grasping or holding instruments.</p>			
Indications for use	The subject devices are intended to be place in the	The subject devices are intended to be placed in	<ul style="list-style-type: none"> • Orthodontic tooth-moving procedures where 	The Orthodontic Bone Anchor (OBA) System is	Same

	mouth for use as an anchor in orthodontic procedures.	the mouth for use as an anchor in orthodontic procedures.	maximum stability is required <ul style="list-style-type: none"> • Patients in their permanent dentition • Patients where dental fixation is not possible (tooth or alveolar loss, trauma) 	indicated for intrusion and extrusion of teeth, distal and mesial movement of teeth, treatment of anterior cross bite and open bite, space closure, 3-D control of teeth.	
Raw material	ASTM F67 ASTM F136-02a	Pure titanium	F67 grade 2 titanium	ASTM-F67 grade 4 ASTM-R136-02a	Same
Design	<p>T-Type</p>  <p>I-Type</p> 	<p>The Bollard</p>  <p>The Bollard with hook</p> 	<p>C-tube plates</p>  <p>Hook plates</p> 	<p>Mesh plate anchor</p> 	<p>Different.</p> <p>In clinical application literature, different shapes of the plates are described in the literature as following; L-shaped, T-shaped, Y-shaped, I-shaped rectangular or triangular comprising 2, 3 or 5 holes for screw fixation.(Reference 1-5)</p> <p>Also, some articles studied the influence of the shape of the bone plate, but it didn't seem to be a significant factor for success.(Reference 1)</p> <p>Finally, the variations in shape mean that the surgeon can select the most appropriate anchor plate according to the bone contour of the implantation site. Therefore, its minor</p>

Y-Type



W-Type



C-palatal Plate



Bondable surface plates



Bracket Plate anchor



4-hole bracket plate anchor



5-hole bracket plate anchor

Domed plate anchor

deviation is acceptable for clinical application.

Intended Use	The subject devices are intended to be place in the mouth for use as an anchor in orthodontic procedures.	-	<p>In cases of dental regulations a C-tube (Chung's microplate with tube) can be fixed in the lateral part of the maxilla or mandible. The eyelet will remain in the buccal sulcus and serves to hold the dental arch wire.</p> <p>The KLS-Martin Ortho Anchorage System is intended to be surgically placed in the mouth for use as an anchor for orthodontic procedures.</p>	The Orthodontic Bone Anchor(OBA) System is intended to be implanted intraorally and used as an anchor for orthodontic procedures.	Same
Dimensions(unit:mm)	Thickness : 0.8/ 1 Length : 13.35 - 40.35	Not Listed	Thickness : 0.6/1.0/1.5	Not Listed	<p>Similar.</p> <p>As literature (Reference 6), C-tube plate, 0.66 of dimension and 14.0 of length, were used. and Synthes OBA domed design</p>

					4 holes, 0.76 of thickness and 13.5 of length, were used. Generally, Anchor plate was selected according to the distance between the implantation site and the dentition by professional.
Surface Treatment	Machined	Machined	Machined	Not Listed	Same
Sterilization	Provided as non-sterile, needs autoclave prior to use. • Temperature : 121 °C • Exposure time : 30 min • Dry time : 15 min	Gamma Radiation ISO 11137-1	Not Listed	Provided as non-sterile, needs autoclave prior to use. Thermal disinfect at 93°C for minimum of 2 minutes and 30 seconds.	Same
Usage	Single use Only	Single use Only	Not Listed	Single use Only	Same
Biocompatibility	Device is biocompatible when used as directed by dental professionals per ISO 10993-1.	Device is biocompatible when used as directed by dental professionals per ISO 10993-1.	Device is biocompatible when used as directed by dental professionals per ISO 10993-1.	Device is biocompatible when used as directed by dental professionals per ISO 10993-1.	Same
mechanical properties	Bending strength (Avg., N·mm): 102.428 Tensile force (Avg., N): 301.814	Bending strength (Avg., N·mm): 97.125 Tensile force (Avg., N): 176.782	Not Listed	Not Listed	Different. Mechanical and physical properties of subject device are compared with primary predicate device where details method, apparatus and results can be found in

					the test report (Bench test report (subject device VS predicate device). Since there is no unknown standard for performance, the results showed that the properties considered were similar when used for intended use.
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The subject device is similar to predicate device in terms of indication for use, design, raw material etc.

The subject device consists of orthodontic anchorage system, as is the predicate device. The mechanical properties and performance of subject device are not significantly _ from the predicate device, as indicated by non-clinical performance testing.

The shape, dimension and mechanical properties are different between the subject device and the primary predicate device. But the variations in shape or dimension mean that the surgeon can select the most appropriate anchor plate according to the bone contour or distance of the implantation site by professional. Also, in terms of mechanical properties, these differences are not significantly difference on its intended use or performance. Therefore, its minor deviation is acceptable for clinical application.

7. Performance Data(Non-Clinical)

The test such as appearance, dimension and bending strength is to verify the performance of the device as it designed. Bending strength was performed according to ISO 9585. All of test results obtained from these tests indicated that Anchor Plate is substantially equivalent to the predicate device in terms of mechanical properties and performance.

The biocompatibility evaluation for the Anchor Plate was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO 10993, 'Biological Evaluation of Medical Devices Part 1:Evaluation and Testing'" May 1, 1995, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices - Part 1 : Evaluation and Testing Within a Risk Management Process" as recognized by FDA. The device of testing included the following tests:

- Genotoxicity, ISO 10993-3(2014)
- Cytotoxicity, ISO 10993-5(2009)
- Implantation, ISO 10993-6(2007)
- Sensitization(GPMT), ISO 10993-10(2010)
- Oral mucous irritation / Intracutaneous reactivity, ISO 10993-10(2010)
- Systemic toxicity(Acute), ISO 10993-11(2006)

Anchor Plate and the primary predicate device were tested for the non-clinical performance including Pullout force with 3-point bending test according to JIS T 0312:2008, Testing methods for bending properties of metallic osteosynthesis devices and tensile force test. For tensile force test, there is no international standard or required guidance, therefore it is performed according to own test method. The results showed that the subject and predicate devices are fundamentally equivalency. Based on the comparative data, subject devices are essentially the same as currently marketed devices for the same indication, with similar physical properties or design, which supports our claim for substantial equivalence. Anchor plate shows no differences in technological characteristics compared to the predicate devices.

8. Substantial Equivalence Discussion

The subject device is similar to predicate device in terms of indication for use, design, raw material etc.

The subject device consists of orthodontic anchorage system, as is the predicate device. The mechanical properties and performance of subject device are not significantly different from the predicate device, as indicated by non-clinical performance testing.

The length and thickness are different between subject device and predicate device.

9. Conclusions

The indications and technological characteristics of anchor plate are very similar to predicate device. Therefore, anchor plate is substantially equivalent to the identified predicate device.