BioMaterials Korea, Inc
℅ Kyung-Hwan Kim
Representative Consultant
SMB Korea
#606, #607, 7, Borame-ro 5ga-gil
Donjak-gu
Seoul, 07071
Korea, South

8/21/23

Re: K222245
Trade/Device Name: ACR Screw System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: OAT
Dated: July 20, 2023
Received: July 21, 2023

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 (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,

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 *(if known)*
K222245

Device Name
ACR Screw System

Indications for Use *(Describe)*
The ACR Screw System is indicated for use as a fixed anchorage point for the attachment of orthodontic appliances to facilitate the orthodontic movement of teeth for use in patients 12 years of age and older. It is used temporarily and is removed after orthodontic treatment is complete. 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.

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K222245

510(k) Summary
For
ACR Screw System

[Complying with 21 CFR 807.92]

I. SUBMISSION SPONSOR

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Email: info@smbkorea.com

III. DATE PREPARED

August 21, 2023

IV. DEVICE

Trade or Proprietary Name:	ACR Screw System
Common or Usual Name:	Sterile Orthodontic Anchorage Screw
Classification Name:	Implant, Endosseous, Orthodontic (872.3640)
Regulatory Class:	II
Product Code:	OAT
Classification Panel:	Dental

V. PREDICATE DEVICE

Primary Predicate Device:
K063495, Orthodontic Anchor Screws of C type and Special type/ BioMaterials Korea, Inc.

Reference Device:
K161335, Dual Top Screw System for orthodontic anchor / Jeil Medical Corporation
K182929, BIO-RAY A-1 Anchor Screw System / Microware Precision Co., Ltd.

VI. DEVICE DESCRIPTION

The ACR Screw System is indicated for use as a fixed anchorage point for the attachment of orthodontic appliances to facilitate the orthodontic movement of teeth. It is used temporarily and is removed after orthodontic treatment is complete. The average temporary implantation period for the anchorage screw is six months. Screws are intended for single use only.

Screws are essentially C-type screw head design and size. Screw diameters and lengths are offered in the following range: thread diameter (1.75 mm) and overall length (11.10 – 15.10 mm). The screw tip has a self-drilling feature for insertion and removal. It is manufactured from a machined piece of Ti-6Al-4V ELI titanium alloy (ASTM F 136-13). These devices are supplied sterile and sterilized by gamma irradiation. This device is individually packaged in a polyethylene bag.

VII. Accessories for the Product, Integral Parts of Package

Not applicable.

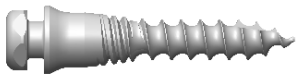
VIII. INDICATION FOR USE

The ACR Screw System is indicated for use as a fixed anchorage point for the attachment of orthodontic appliances to facilitate the orthodontic movement of teeth for use in patients 12 years of age and older. It is used temporarily and is removed after orthodontic treatment is complete. The screws are intended for single use only.

IX. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

<Substantial Equivalence to Predicate Devices Table – ACR Screw System>

	SUBJECT Device	**Primary PREDICATE Device (K063495)**	**REFERENCE Device (K161335)**	**REFERENCE Device (K182929)**
Manufacturer	**BioMaterials Korea, Inc.**	**BioMaterials Korea, Inc.**	**Jeil Medical Corporation**	**Microware Precision Co., Ltd.**
Trade Name	ACR Screw System	Orthodontic Anchor Screws of C type and Special type	Dual Top Screw System	BIO-RAY A-1 Anchor Screw System
Regulation Description	Implant, Endosseous, Orthodontic	Implant, Endosseous, Orthodontic	Implant, Endosseous, Orthodontic	Implant, Endosseous, Orthodontic
Regulation Number	21 CFR 872.4760	21 CFR 872.4760	21 CFR 872.4760	21 CFR 872.4760
Product Code	OAT	OAT	OAT	OAT
Class	II	II	II	II
Indications for Use	The ACR Screw System is indicated for use as a fixed anchorage point for the attachment of orthodontic appliances to facilitate the orthodontic movement of teeth for use in patients 12 years of age and older. It is used temporarily and is removed after orthodontic treatment is complete. The screws are intended for single use only.	Orthodontic Anchor Screws of C type and Special Type are intended for use as 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.	The BIO-RAY A-1 Anchor Screw System is intended to provide fixed anchorage for attachment of orthodontic appliances intended to facilitate the orthodontic movement of teeth. It's used temporarily and intended to be removed after orthodontic treatment has been completed. The screw is intended for single use only.
Principle of Operation	The ACR Screw System is	Orthodontic anchorage	Orthodontic anchorage	Orthodontic anchorage

	SUBJECT Device	**Primary PREDICATE Device (K063495)**	**REFERENCE Device (K161335)**	**REFERENCE Device (K182929)**
Manufacturer	**BioMaterials Korea, Inc.**	**BioMaterials Korea, Inc.**	**Jeil Medical Corporation**	**Microware Precision Co., Ltd.**
	placed in both jaws to help the orthodontist move the right teeth and keep the wrong teeth from moving in the wrong direction.	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.	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.	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.
Raw material	Ti-6Al-4V ELI Titanium Alloy (ASTM F 136)	Ti-6Al-4V ELI Titanium Alloy (ASTM F 136)	Ti-6Al-4V ELI Titanium Alloy (ASTM F 136)	Stainless steel 316L (ASTM F138); Ti-6Al-4V ELI Titanium Alloy (ASTM F 136)
Form	Orthodontic Anchorage Screw	Orthodontic Anchorage Screw	Orthodontic Anchorage Screw	Orthodontic Anchorage Screw
Head Structure	[C type] 	[C type]  [CT type] 	[JA]  [JF] 	[A-1PI]  [A-1 HI] 

	SUBJECT Device	Primary PREDICATE Device (K063495)	REFERENCE Device (K161335)	REFERENCE Device (K182929)
Manufacturer	**BioMaterials Korea, Inc.**	**BioMaterials Korea, Inc.**	**Jeil Medical Corporation**	**Microware Precision Co., Ltd.**
			[JB]  [G1]  [G2]  [JK]  [JD]  [MIM]	[A-1 Torque]   [Bracket]  [IZC]  [M]  [V]

	SUBJECT Device	**Primary PREDICATE Device (K063495)**	**REFERENCE Device (K161335)**	**REFERENCE Device (K182929)**
Manufacturer	**BioMaterials Korea, Inc.**	**BioMaterials Korea, Inc.**	**Jeil Medical Corporation**	**Microware Precision Co., Ltd.**
			 [JS] 	
Thread Diameter × Overall Length	Diameter by length: Ø1.75 mm × 11.10, 13.10, 15.10 mm	Length: 4.0 to 11.0 mm Diameter: Ø1.15 to Ø2.0 mm	Length: 5.0 mm to 16.0 mm Diameter: Ø1.3 mm to Ø2.5 mm	Length: 8.0, 9.0, 10.0, 11.0, 12.0, 13.0, 14.0, 15.0, 16.0, 17.0 mm Diameter: Ø1.5 mm to Ø2.0 mm
Surface Treatment	No surface treatment	No surface treatment	Anodized	Stainless steel screws: Electrolytic polishing; Titanium alloy screws: Anodizing
Sterilization	Sterile (Gamma)	Non-sterile; Steam sterilization prior to use	Non-Sterile (Steam sterilized by user) or Gamma-Sterilized	Non-sterile; Steam sterilization prior to use
Single Use/Reuse	Single use Only	Single use Only	Single use Only	Single use Only
Biocompatibility	Biocompatible according to ISO 10993-1	Biocompatible according to ISO 10993-1	Biocompatible according to ISO 10993-1	Biocompatible according to ISO 10993-1
Performance Testing	ASTM F543-17	ASTM F543-17	ASTM F543-17	ASTM F543-17
SE	The information provided in these 510(k) submissions demonstrates that the ACR Screw System is substantially equivalent to the predicate devices with respect to indications for use, device design, function, and performance with respect to			

	SUBJECT Device	Primary PREDICATE Device (K063495)	REFERENCE Device (K161335)	REFERENCE Device (K182929)
Manufacturer	**BioMaterials Korea, Inc.**	**BioMaterials Korea, Inc.**	**Jeil Medical Corporation**	**Microware Precision Co., Ltd.**
	technological characteristics. The predicate devices are made of the same material as the subject device, titanium alloy (ASTM F136), the same material as our device. Differences between the subject device and the predicate devices are not expected to affect the overall performance of the device. There are minor differences in thread diameter, overall length, and head design between the subject and predicate devices. However, there is an additional thread length in the subject device compared to the primary predicate device. The difference in length is slight, but the Dual Top Screw System and the BIO-RAY A-1 Anchor Screw System have been used by Jeil Medical Corporation and Microware Precision Co., Ltd. to support these thread lengths; it does not introduce a significantly different design. The technological differences between the subject device and the predicate devices do not impact substantial equivalence, and substantial equivalence is demonstrated by testing in accordance with ISO 19023 and ASTM F543. Based on the foregoing, the subject device, the ACR Screw System, is determined to be substantially equivalent (SE) to the predicate devices.			

X. NONCLINICAL TEST

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

Mechanical Properties

Mechanical testing was performed to determine the pull-out, torsion, and torque of the screw in accordance with ISO 19023:2018, Dentistry – Orthodontic anchor screws; and ASTM F543-17, Standard Specification and Test Methods for Metallic Medical Anchor screw.

Biocompatibility

The ACR Screw System is manufactured using the same manufacturing process and proven materials as the orthodontic screw previously cleared under K063495. Therefore, it is believed that additional biocompatibility testing is not necessary to support the biological safety of the ACR Screw System.

The biocompatibility evaluation and testing were 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 10993-5, Biological evaluation of medical device-Part 5: Tests for in vitro cytotoxicity.
- ISO 10993-12, Biological evaluation of medical device-Part 12: Sample preparation and reference materials."

Sterilization Testing

Sterilization validation testing has been performed on the ACR Screw System in accordance with ISO11137-1:2006/Amd 2:2018, ISO 11137-2:2013/Amd 1:2022 and ISO 11137-3:2017. Test results showed that the SAL of 10^{-6} was achieved and all test requirements were met.

Bacterial Endotoxin Testing

Bacterial endotoxin testing is performed in accordance with ANSI/AAMI ST72:2011 using the Limulus Amebocyte Lysate (LAL) pyrogen test method at a test limit of 0.06 EU/mL. Testing met predetermined acceptance criteria. Routine monitoring of endotoxins in the manufacturing process is performed quarterly.

Shelf-Life Testing

The ACR Screw System, following to gamma sterilization and packaging was subjected to sterile barrier testing to validate a shelf life of 3 years according to ISO 11607-1:2019, "Packaging for terminally sterilized medical devices – Part 1: Requirements for materials,

sterile barrier systems and packaging systems" and ISO 11607-2:2019, "Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes" confirm the stability and effectiveness of the packaging of the sterilized product during the shelf life, by evaluating changes due to accelerated aging, according to ASTM F1980-21, "Standard Guide for Accelerated Aging of Sterile Barrier Systems and Medical Devices".

The ACR Screw System was evaluated using the sterility, peel strength, dye penetration, and burst tests. The device met the acceptance criteria for each test.

XI. CLINICAL TESTS

Clinical data was not provided for ACR Screw System.

XII. CONCLUSIONS

The ACR Screw System and the predicate devices have the substantially equivalent indications for use, the same raw materials, the same range of physical dimensions, and the same characteristics. In addition, the substantial equivalence of the predicate devices has been confirmed through non-clinical testing. Therefore, the ACR Screw System has been demonstrated to be equivalent to the predicate devices.