February 13, 2020

MegaGen Implant CO., Ltd.
You Jung Kim
Chief Researcher
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Daegu, 42921
REPUBLIC OF KOREA

Re: K192614
Trade/Device Name: Meg-Ball Attachment System, Meg-Loc Abutment, Meg-Magnet Abutment
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: November 14, 2019
Received: November 18, 2019

Dear You Jung 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,

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)*

K192614

Device Name

Meg-Ball Attachment System, Meg-Loc Abutment, Meg-Magnet Abutment

Indications for Use *(Describe)*

The Meg-Ball Attachment System, Meg-Loc Abutment, Meg-Magnet Abutment is intended to be used in the upper or lower jaw and used for supporting tooth replacements to restore chewing function. Intended for fully edentulous jaw retaining a tissue supported overdenture.

The abutments in combination with endosseous implants are used as the foundation for anchoring tooth replacements in either jaw. The attachments are used in fixed overdenture restorations that can be attached with a snap-in system.

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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K192614

510(k) Summary

Date: Feb 13, 2020

1. Applicant / Submitter

MegaGen Implant Co., Ltd.
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Daegu, Republic of Korea
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2. Submission Correspondent

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3. Device

- Trade Name: Meg-Ball Attachment System, Meg-Loc Abutment, Meg-Magnet Abutment
- Common Name: Endosseous Dental Implant Abutment
- Classification Name: Abutment, Implant, Dental, Endosseous
- Classification Product Code: NHA
- Classification regulation: Class II, 21 CFR 872.3630

4. Predicate Device

- Primary Predicate Device:
  K182091 – Osstem Abutment System

- Reference Devices:
  K161689– Osstem Implant System – Abutment
  K162867 - MagDen Dental Implant System
  K123988 – AnyOne Internal Implant System
  K151789 - LOCATOR F-Tx Implant Attachment System
  K101890 – Ball Abutment System

5. Description

Meg-Ball Attachment System, Meg-Loc Abutment, Meg-Magnet Abutment is a superstructure of a dental implant system to provide support for prosthetic restorations. It is intended to be used in implant-retained and removable overdenture restorations where the patient is fully edentulous.

Meg-Ball Attachment System, Meg-Loc Abutment, Meg-Magnet Abutment is compatible with the following FDA cleared MegaGen Implant system.

Manufacturer	Device Name	510(k) Number	Connection	Diameter (mm)
MegaGen Implant Co., Ltd.	AnyRidge Internal Fixture	K110955, K122231	Internal Hex	4.0, 4.4, 4.9, 5.4, 5.9, 6.4, 6.9, 7.4, 7.9, 8.4
	AnyOne Internal Fixture	K123988	Internal Hex	3.9, 4.3, 4.8, 5.3, 5.8, 6.3, 6.8, 7.3, 7.8, 8.3
	AnyRidge Octa 1 Fixture	K182448	Internal Octa	3.3, 3.7, 4.1, 4.4, 4.8
	ExFeel Internal Fixture	K052369	Internal Hex	4.8

The subject device is consisted of the following devices.

Component		Content		
Meg-Ball Attachment System	**Meg-Ball Abutment**	Description		Meg-ball Abutment is intended to be used in completely edentulous jaws and connects to an overdenture to allow its insertion and removal. Meg-ball abutment has a ball shaped.
		Material Composition		Ti-6A1-4V ELI
		Diameter		2.91, 3.13, 3.40, 3.50 mm
		Head Diameter		2.25 mm
		Head Length		4.15 mm
		Gingival Heights		0.3, 0.8, 1.8, 2.8, 3.8, 4.8, 5.8 mm
		Total Length		9.5, 10, 10.1, 10.6, 10.65, 10.75, 11, 11.15, 11.25, 11.6, 12, 12.15, 12.25, 12.6, 13, 13.15, 13.25, 13.6, 14, 14.15, 14.25, 14.6, 15, 15.15, 15.25, 15.6, 16.15, 16.25 mm
		Angulation		Straight
		Compatible Implant System		AnyRidge Internal Implant System AnyOne Internal Implant System AnyRidge Octa 1 Implant System ExFeel Internal Implant System
	Metal Housing	**Metal Cap**	Description	Metal cap has shape of cap to protect and hold the retentive ring. It is fixed into the denture and is applied to Meg-ball abutment to stabilize the denture.
			Material Composition	Ti-6A1-4V ELI
			Diameter	5.0 mm
			Height	4.0 mm
		Retentive Ring	Description	Retentive ring has shape of ring to connect to Meg-ball abutment. It is inserted into the metal cap and serves as a buffer for the abutment and denture stabilizing, and can be replaced.
			Material	Fluorinated Rubber

			Composition	
			Diameter	4.5 mm
			Height	1.5 mm
Meg-Loc Abutment			Description	Meg-Loc Abutment is intended to be used in completely edentulous jaws and connects to an overdenture to allow its insertion and removal. Meg-Loc abutment has a truncated head.
			Material Composition	Ti-6A1-4V ELI
			Diameter (Head)	3.89 mm
			Diameter (Body)	2, 2.45, 3.14, 3.4, 3.5 mm
			Gingival Height	0.3, 0.8, 1.8, 2.8, 3.8, 4.8, 5.8 mm
			Total Length	6.85, 7.35, 7.45, 7.95, 8, 8.1, 8.35, 8.5, 8.6, 8.95, 9.35, 9.5, 9.6, 9.95, 10.35, 10.5, 10.6, 10.95, 11.35, 11.5, 11.6, 11.95, 12.35, 12.5, 12.6, 12.95, 13.5, 13.6 mm
			Angulation	Straight
			Compatible Implant System	AnyRidge Internal Implant System AnyOne Internal Implant System AnyRidge Octa 1 Implant System ExFeel Internal Implant System
Meg-Magnet Abutment			Description	Meg-Magnet Abutment is intended to be used in completely edentulous jaws and connects to an overdenture to allow its insertion and removal using the magnetic force of the magnet attachment (D356767). Meg-Magnet abutment has a flat head.
			Material Composition	Stainless Steel
			Surface Treatment	TiN coating
			Diameter (Head)	4.5, 5.0 mm
			Diameter (Body)	2, 2.45, 3.56, 4.86 mm
			Gingival Height	0.3, 0.8, 1.8, 2.8, 3.8, 4.8, 5.8 mm
			Total Length	5.65, 5.85, 6.15, 6.75, 6.8, 6.9, 7.15, 7.3, 7.4, 7.75, 8.15, 8.3, 8.4, 8.75, 9.15, 9.3, 9.4, 9.75, 10.15, 10.3, 10.4, 10.75, 11.3, 11.4 mm
			Angulation	Straight
			Compatible Implant System	AnyRidge Internal Implant System AnyOne Internal Implant System AnyRidge Octa 1 Implant System ExFeel Internal Implant System

6. Indication for use

Meg-Ball Attachment System, Meg-Loc Abutment, Meg-Magnet Abutment is intended to be used in the upper or lower jaw and used for supporting tooth replacements to restore chewing function. Intended for fully edentulous jaw retaining a tissue supported overdenture.

The abutments in combination with endosseous implants are used as the foundation for anchoring tooth replacements in either jaw. The attachments are used in fixed overdenture restorations that can be attached with a snap-in system.

7. Basis for Substantial Equivalence

Meg-Ball Attachment System, Meg-Loc Abutment, Meg-Magnet Abutment is substantially equivalent to the predicate devices in terms of intended use, technical characteristics, function, and performance. They are made of the same material (except for the retentive ring) and have a similar design. The size range of subject device slightly differ from the predicate devices however it is very minor not affecting substantial equivalence.

The subject device is composed of the straight type abutments that are used for supporting the overdenture, while the predicate & reference devices address complete dental implant system including various fixtures and abutments. For this reason, the indication for use statements between subject and predicate devices are different but, the proposed indication is available to apply to predicate/reference devices as well, since the submission device is a sub-set of devices included in the predicate & reference device. Also, the indications for use statements of the subject device and the predicate and reference devices have the same intended use as they are intended to provide the prosthetic support for dental restorations such as crown, bridges, and overdenture to restore patient's chewing function. This minor difference in wording does not affect the substantial equivalence of the subject device. Therefore, the indication for use statement of subject device is substantially equivalent to the predicate device.

In order to demonstrate the difference does not raise any new issues, each performance test on the subject and predicate device have been performed in consideration of the worst case according to 'Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutment' to figure out physical property (e.g. retentive force). Fatigue testing was not conducted based on above FDA Guidance Document because the proposed abutments is straight type. The subject abutment is intended for straight implantation, and does not receive single load, because it used for supporting the overdenture for which the load is dispersed to the full denture. The test result shows that the performance of subject device supports the substantial equivalence to the predicate device.

Based on the detailed comparison charts below and test results provided in this submission, we conclude that the subject device is substantially equivalent to the predicate devices.

Meg-Ball Attachment System

- **Meg-Ball Abutment**

	Subject Device	Predicate Device	Reference Device 1	Reference Device 2	Reference Device 3
510(k) No.	K192614	K182091	K161689	K123988	K101890
Device Name	**Meg-Ball Abutment** For Meg-Ball Attachment System, Meg-Loc Abutment, Meg-Magnet Abutment	**Stud Abutment** For Osstem Abutment System	**Stud Abutment** For OSSTEM Implant System-Abutment	**Ball Abutment** For AnyOne™ Internal Implant System	**Ball Abutment** For Ball Abutment System
Manufacturer	MegaGen Implant Co., Ltd.	Osstem Implant Co., Ltd.	Osstem Implant Co., Ltd.	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.
Indications for Use Statement	Meg-Ball Attachment System, Meg-Loc Abutment, Meg-Magnet Abutment is intended to be used in the upper or lower jaw and used for supporting tooth replacements to restore chewing function. Intended for fully edentulous jaw retaining a tissue supported overdenture. The abutments in combination with endosseous implants are used as the foundation for anchoring tooth replacements in either jaw. The attachments are used in fixed overdenture restorations that can be attached with a snap-in system.	Osstem Abutment System is intended for use with a dental implant to provide support for Prosthetic restorations such as crowns, bridges, or overdentures.	The OSSTEM Implant System - Abutment is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.	The AnyOne Internal Implant System is intended to be surgically placed in the maxillary or mandibular molar areas for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function. Smaller implants (less than 6.0 mm) are dedicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region and are indicated for delayed loading.	The Ball Abutment Systems are used for implant retained mucosa-supported restorations, such as overdentures where the patient is fully edentulous in the arch to be restored. There are two types of Ball Abutment system, internal and external type, and the ball abutment technique is used on Ball Abutment System implants in the maxille or mandible.
Design					
Diameter	2.91, 3.13, 3.4, 3.5 mm	3.5 mm	3.5 mm	3.4 mm	2.85, 3.5, 4. 1, 5.0, 6.0mm
Head Diameter	2.25 mm	1.7 mm	2.25mm	2.25 mm	2.25mm
Head Length	4.15 mm	2.5 mm	3.35mm	3.8mm	4.0 mm
Total Length	9.5, 10, 10.1, 10.6, 10.65, 10.75, 11, 11.15, 11.25, 11.6, 12, 12.15, 12.25, 12.6, 13, 13.15, 13.25, 13.6, 14, 14.15, 14.25, 14.6, 15, 15.15, 15.25, 15.6, 16.15, 16.25	8.5, 8.9, 9.5, 9.9, 10.5, 10.9, 11.5, 11.9, 12.5, 12.9, 13.5, 13.9	9.35, 9.75, 10.35, 10.75, 11.35, 11.75, 12.35, 12.75, 13.35, 13.75, 14.35, 14.75	10.25, 11.5, 13.5, 15.5	9.15, 9.65, 9.85, 11.1, 11.65, 11.85, 13.1, 13.65, 13.85, 15.1
Compatible Implant System	AnyRidge Internal Implant System AnyOne Internal Implant System AnyRidge Octa 1 Implant System	TS SA Fixture System SS SA Fixture System US SA Fixture System	TS Fixture System	AnyOne Internal Implant System	ExFeel Implant System EZ Plus Implant System Rescue External Implant System

	ExFeel Internal Implant System	MS SA Implant System			
Material	Ti-6A1-4V ELI	Ti-6A1-4V ELI	Ti-6A1-4V ELI	Ti-6Al-4V ELI	Ti-6Al-4V ELI
Surface Treatment	Machined surface	Partial TiN coating	Partial TiN coating	Machined surface	Machined surface
Sterilization	Non-sterile	Non-sterile	Non-sterile	Non-sterile	Non-sterile
Abutment Angle	Straight	Straight	Straight	Straight	Straight (External Type)
Principle of Operation	This product is generally applied to prosthetic procedure for overdentures. The head part is where connected to overdenture with attachment and the screw part is connected directly to the endosseous dental implant by their threaded part.	This product is generally applied to prosthetic procedure for overdentures. The head part is where connected to overdenture with attachment and the screw part is connected directly to the endosseous dental implant by their threaded part.	This product is generally applied to prosthetic procedure for overdentures. The head part is where connected to overdenture with attachment and the screw part is connected directly to the endosseous dental implant by their threaded part.	This product is generally applied to prosthetic procedure for overdentures. The head part is where connected to overdenture with attachment and the screw part is connected directly to the endosseous dental implant by their threaded part.	This product is generally applied to prosthetic procedure for overdentures. The head part is where connected to overdenture with attachment and the screw part is connected directly to the endosseous dental implant by their threaded part.

Substantial Equivalence Discussion

1. **Similarities**

The subject device has similar characteristic for the following compared to the predicate/reference devices.

- Design, Head Diameter, Material, Surface Treatment, Sterilization, Angle and Principle of Operation

2. **Differences**

The subject device has the different characteristic for the following compared to the predicate devices.

- Indications for Use – See Section 7 (page 4/13)
- Diameter, Head Diameter and Head Length

The diameter of 3.4, 3.5mm in subject device is same size as predicate/reference devices. The diameter range of the subject device is slightly different with predicate/reference devices by addition of diameter 2.91mm and 3.13.mm in subject device but it can be covered by reference device 3 and the variety of the size can be possible to operate more precise treatment to meet each patient's condition. The head length of subject device is slightly longer than predicate/reference devices. However, all of these size differences do not cause a change in the intended use of the device since the size difference is very minor.

3. **Discussion**

In order to demonstrate the differences do not raise an issue in substantial equivalence, each performance test on the subject and predicate device have been performed to figure out physical property (e.g. retentive force) with appropriate attachment as intended. Fatigue testing is not considered based on FDA Guidance Document being as proposed abutments is straight type. The subject abutment is intended for straight implantation, and is not received single load, because it used for supporting the overdenture that means load is dispersed to the full denture. The test result shows that the performance of subject device supports the substantial equivalence to the predicate device.

In conclusion, the subject device is substantially equivalent to the predicate device since the subject and predicate device have in common in indication for use, design, material, function; and the differences are minor and theses have been identified via the performance test the differences do not impact substantial equivalence.

- **Metal Cap**

	Subject Device	Predicate Device	Reference Device 1	Reference Device 2
510(k) Number	K192614	K182091	K161689	K182091
Device Name	**Metal Cap** For Meg-Ball Attachment System, Meg-Loc Abutment, Meg-Magnet Abutment	**O-ring Retainer Cap** For Osstem Abutment System	**O-ring Retainer Cap** For OSSTEM Implant System-Abutment	**Port Male Cap** For Osstem Abutment System
Manufacturer	MegaGen Implant Co., Ltd.	Osstem Implant Co., Ltd.	Osstem Implant Co., Ltd.	Osstem Implant Co., Ltd.
Indications for Use Statement	The Meg-Ball Attachment System, Meg-Loc Abutment, Meg-Magnet Abutment is intended to be used in the upper or lower jaw and used for supporting tooth replacements to restore chewing function. Intended for fully edentulous jaw retaining a tissue supported overdenture. The abutments in combination with endosseous implants are used as the foundation for anchoring tooth replacements in either jaw. The attachments are used in fixed overdenture restorations that can be attached with a snap-in system.	Osstem Abutment System is intended for use with a dental implant to provide support for Prosthetic restorations such as crowns, bridges, or overdentures.	The OSSTEM Implant System - Abutment is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.	Osstem Abutment System is intended for use with a dental implant to provide support for Prosthetic restorations such as crowns, bridges, or overdentures.
Design				
Diameter	5 mm	3.95mm	5 mm	5.5 mm
Height	4 mm	2.9 mm	3.9mm	2.25 mm
Material	Ti-6A1-4V ELI	Titanium Gr. 3	Titanium Gr. 3	Ti-6A1-4V ELI
Surface treatment	Machined surface	Machined surface	Machined surface	Machined surface
Sterilization	Non-sterile	Non-sterile	Non-sterile	Non-sterile
Principle of operation	This product is generally applied to prosthetic procedure for overdentures. It is inserted and fixed into denture; and applied to ball type abutment to stabilize the overdenture.	This product is generally applied to prosthetic procedure for overdentures. It is inserted and fixed into denture; and applied to stud type abutment to stabilize the overdenture.	This product is generally applied to prosthetic procedure for overdentures. It is inserted and fixed into denture; and applied to stud type abutment to stabilize the overdenture.	This product is generally applied to prosthetic procedure for overdentures. It is inserted and fixed into denture; and applied to port type abutment to stabilize the overdenture.

Substantial Equivalence Discussion

1. Similarities

The subject device has similar characteristic for the following compared to the predicate/reference devices.

- Design, Diameter, Material, Surface Treatment, Sterilization and Principle of Operation

2. Differences

The subject device has the different characteristic for the following compared to the predicate/reference devices.

- Indications for Use – See Section 7 (page 4/13)
- Height

The height of subject device is slightly longer than predicate devices; there is a 0.1mm difference between reference device 1. It does not cause a matter in substantial equivalence since the size difference is minor.

3. Discussion

In order to demonstrate the difference does not raise an issue in substantial equivalence, each performance test on the subject and predicate device have been performed to figure out physical property (e.g. retentive force) with appropriate abutment as intended. The test result shows that the performance of subject device supports the substantial equivalence to the predicate device.

In conclusion, the subject device is substantially equivalent to the predicate device since the subject and predicate device have in common in indication for use, design, material, function; and the differences are minor and theses have been identified via the performance test the differences do not impact substantial equivalence.

- **Retentive Ring**

	Subject Device	Predicate Device	Reference Device
510(k) Number	K192614	K182091	K161689
Device Name	**Retentive Ring** For Meg-Ball Attachment System, Meg-Loc Abutment, Meg-Magnet Abutment	**O-ring** For Osstem Abutment System	**O-ring** For OSSTEM Implant System-Abutment
Manufacturer	MegaGen Implant Co., Ltd.	Osstem Implant Co., Ltd.	Osstem Implant Co., Ltd.
Indications for Use Statement	The Meg-Ball Attachment System, Meg-Loc Abutment, Meg-Magnet Abutment is intended to be used in the upper or lower jaw and used for supporting tooth replacements to restore chewing function. Intended for fully edentulous jaw retaining a tissue supported overdenture. The abutments in combination with endosseous implants are used as the foundation for anchoring tooth replacements in either jaw. The attachments are used in fixed overdenture restorations that can be attached with a snap-in system.	Osstem Abutment System is intended for use with a dental implant to provide support for Prosthetic restorations such as crowns, bridges, or overdentures.	The OSSTEM Implant System - Abutment is intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.
Design			
Diameter	4.5mm	3.5 mm	4.6mm
Height	1.5 mm	Not known	1.5 mm
Material	Fluorinated Rubber	NBR (Acrylonitrile & Butadiene Polymer)	NBR (Acrylonitrile & Butadiene Polymer)
Sterilization	Non-sterile	Non-sterile	Non-sterile
Principle of operation	This product is generally applied to prosthetic procedure for overdentures. It is inserted into the Metal Cap and serves as a buffer for ball type abutment and denture stabilizing.	This product is generally applied to prosthetic procedure for overdentures. It is inserted into the O-ring Retainer Cap and serves as a buffer for stud type abutment and denture stabilizing.	This product is generally applied to prosthetic procedure for overdentures. It is inserted into the O-ring Retainer Cap and serves as a buffer for stud type abutment and denture stabilizing.

Substantial Equivalence Discussion

1. **Similarities**
   The subject device has similar characteristic for the following compared to the predicate devices.
   - Design, Height, Sterilization, and Principle of Operation
2. **Differences**
   The subject device has the different characteristic for the following compared to the predicate devices.
   - Indications for Use – See Section 7 (page 4/13)
   - Diameter
     The diameter of subject device is slightly different with predicate devices; there is a 0.1mm difference between reference device and the subject device lies within the combined range of the predicate devices and reference device. This difference does not cause a matter in substantial equivalence since the size difference is minor.
   - Material
     The material of subject device is different with predicate devices but the biocompatibility testing has been performed in accordance with ISO 10993-1.
3. **Discussion**
   In order to demonstrate the differences do not raise an issue in substantial equivalence, each performance test on the subject and predicate device have been performed to figure out physical property (e.g. retentive force) with appropriate attachment and abutment as intended. The biocompatibility test has been conducted as well for demonstrating the substantial equivalence of the material difference. The tests result show that the performance and biocompatibility of subject device support the substantial equivalence to the predicate device.
   In conclusion, the subject device is substantially equivalent to the predicate device since the subject and predicate device have in common in indication for use, design, function, etc.; and the differences have been identified via the tests and do not impact substantial equivalence.

- **Meg-Loc Abutment**

	Subject Device	Predicate Device	Reference Device	Reference Device
510(k) No.	K192614	K182091	K123988	K151789
Device Name	**Meg-Loc Abutment** For Meg-Ball Attachment System, Meg-Loc Abutment, Meg-Magnet Abutment	**Port Abutment** For Osstem Abutment System	**Meg-Rhein Abutment** For AnyOne™ Internal Implant System	**LOCATOR F-Tx** For LOCATOR F-Tx Attachment System
Manufacturer	MegaGen Implant Co., Ltd.	Osstem Implant Co., Ltd.	MegaGen Implant Co., Ltd.	Zest Anchors, LLC
Indications for Use Statement	The Meg-Ball Attachment System, Meg-Loc Abutment, Meg-Magnet Abutment is intended to be used in the upper or lower jaw and used for supporting tooth replacements to restore chewing function. Intended for fully edentulous jaw retaining a tissue supported overdenture. The abutments in combination with endosseous implants are used as the foundation for anchoring tooth replacements in either jaw. The attachments are used in fixed overdenture restorations that can be attached with a snap-in system.	Osstem Abutment System is intended for use with a dental implant to provide support for Prosthetic restorations such as crowns, bridges, or overdentures.	The AnyOne Internal Implant System is intended to be surgically placed in the maxillary or mandibular molar areas for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function. Smaller implants (less than 6.0 mm) are dedicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region and are indicated for delayed loading.	The LOCATOR® F-Tx Attachment System is designed to support fixed, partial or full arch restorations on endosseous dental implants in the mandible or maxilla for the purpose of restoring masticatory function. It is used in fixed hybrid restorations that can be attached with a snap-in system.
Design				
Diameter	3.89 mm	3.5, 3.7, 4.1, 4.8, 5.1 mm	3.4 mm	3.0 mm to 7.0 mm
Gingival Height	0.3, 0.8, 1.8, 2.8, 3.8, 4.8, 5.8mm	1, 2, 3, 4, 5, 6, 7 mm	0.3, 1.3, 3.3, 5.3mm	1, 2, 3, 4, 5, 6 mm
Total Length	6.85, 7.35, 7.45, 7.95, 8, 8.1, 8.35, 8.5, 8.6, 8.95, 9.35, 9.5, 9.6, 9.95, 10.35, 10.5, 10.6, 10.95, 11.35, 11.5, 11.6, 11.95, 12.35, 12.5, 12.6, 12.95, 13.5, 13.6	Unknown	8.4, 8.9, 9.9, 10.9, 11.9, 12.9, 13.9	Unknown
Compatible Implant System	AnyRidge Internal Implant System AnyOne Internal Implant System AnyRidge Octa 1 Implant System ExFeel Internal Implant System	TS SA Fixture System SS SA Fixture System US SA Fixture System MS SA Implant System	AnyOne Internal Implant System	Astra Tech BioHorizons Biomet 3i Camlog Dentsply MIS Implants Nobel Biocare Straumann Zimmer
Material	Ti-6A1-4V ELI	Ti-6A1-4V ELI	Ti-6Al-4V ELI	Ti-6A1-4V ELI
Surface Treatment	Machined surface	Partial TiN coating	Machined surface	TiCN or TiN coating
Sterilization	Non-sterile	Non-sterile	Non-sterile	Non-sterile
Abutment Angle	Straight	Straight	Straight	Straight
Principle of Operation	This product is generally applied to prosthetic	This product is generally applied to prosthetic	This product is generally applied to prosthetic	This product is generally applied to prosthetic

	procedure foroverdentures. The head part is where connected to overdenture with attachment and the screw part is connected directly to the endosseous dental implant by their threaded part.	procedure foroverdentures. The head part is where connected to overdenture with attachment and the screw part is connected directly to the endosseous dental implant by their threaded part.	procedure foroverdentures. The head part is where connected to overdenture with attachment and the screw part is connected directly to the endosseous dental implant by their threaded part.	procedure foroverdentures. The head part is where connected to overdenture with attachment and the screw part is connected directly to the endosseous dental implant by their threaded part.

Substantial Equivalence Discussion

1. Similarities

The subject device has similar characteristic for the following compared to the predicate/reference devices.

- Design, Material, Surface Treatment, Sterilization, Angle and Principle of Operation

2. Differences

The subject device has the different characteristic for the following compared to the predicate/reference devices.

- Indications for Use – See Section 7 (page 4/13)
- Diameter and Gingival Height

The diameter of subject device is slightly different with predicate/reference devices however the subject device lies within the range of the predicate device. The gingival height range of the subject device is slightly different with predicate/reference devices however the subject device lies within the combined range of the predicate/reference devices. Also, these differences do not cause a matter in substantial equivalence since size difference is minor.

3. Discussion

In order to demonstrate the differences do not raise an issue in substantial equivalence, each performance test on the subject and predicate device have been performed to figure out physical property (e.g. retentive force) with appropriate attachment as intended. Fatigue testing is not considered based on FDA Guidance Document being as proposed abutments is straight type. The subject abutment is intended for straight implantation, and is not received single load, because it used for supporting the overdenture that means load is dispersed to the full denture. The test result shows that the performance of subject device is verified and supports the substantial equivalence to the predicate device.

In conclusion, the subject device is substantially equivalent to the predicate device since the subject and predicate device have in common in indication for use, design, material, function; and the differences have been identified via the performance test and the differences do not impact substantial equivalence.

- **Meg-Magnet Abutment**

	Subject Device	Predicate Device
510(k) No.	K192614	K162867
Device Name	**Meg-Magnet Abutment** For Meg-Ball Attachment System, Meg-Loc Abutment, Meg-Magnet Abutment	**MagDen Mini Abutment** for MagDen Dental Implant System
Manufacturer	MegaGen Implant Co., Ltd.	SHINHUNG MST Co., Ltd.
Indications for Use Statement	The Meg-Ball Attachment System, Meg-Loc Abutment, Meg-Magnet Abutment is intended to be used in the upper or lower jaw and used for supporting tooth replacements to restore chewing function. Intended for fully edentulous jaw retaining a tissue supported overdenture. The abutments in combination with endosseous implants are used as the foundation for anchoring tooth replacements in either jaw. The attachments are used in fixed overdenture restorations that can be attached with a snap-in system.	The MagDen Dental Implant System is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, and to restore the patient's chewing function.
Design		
Diameter	4.5, 5.0mm	3.8, 4.0, 4.2 mm
Gingival Height	0.3, 0.8, 1.8, 2.8, 3.8, 4.8, 5.8mm	Not Known
Total Length	5.65, 5.85, 6.15, 6.75, 6.8, 6.9, 7.15, 7.3, 7.4, 7.75, 8.15, 8.3, 8.4, 8.75, 9.15, 9.3, 9.4, 9.75, 10.15, 10.3, 10.4, 10.75, 11.3, 11.4	4.3, 4.8, 5.3, 5.5, 5.8, 6.0, 6.3, 6.5, 6.8, 7.0, 7.3, 7.5, 7.8, 8.0, 8.5, 9.0
Compatible Implant System	AnyRidge Internal Implant System AnyOne Internal Implant System AnyRidge Octa 1 Implant System ExFeel Internal Implant System	MagDen Dental Implant System
Material	Stainless Steel	Stainless Steel
Surface Treatment	TiN coating	TiN coating
Sterilization	Non-sterile	Non-sterile
Abutment Angle	Straight	Straight
Principle of Operation	This product is generally applied to prosthetic procedure for overdentures. The head part is where connected to overdenture with attachment and the screw part is connected directly to the endosseous dental implant by their threaded part.	This product is generally applied to prosthetic procedure for overdentures. The head part is where connected to overdenture with attachment and the screw part is connected directly to the endosseous dental implant by their threaded part.

Substantial Equivalence Discussion

1. Similarities

The subject device has similar characteristic for the following compared to the predicate device.

- Design, Material, Surface Treatment, Sterilization, Angle and Principle of Operation.

2. Differences

The subject device has the different characteristic for the following compared to the predicate device.

- Indications for Use – See Section 7 (page 4/13)
- Diameter

  The diameter of subject device is slightly larger than predicate device, however it does not cause a matter in substantial equivalence since the size difference is minor.

3. Discussion

In order to demonstrate the difference does not raise an issue in substantial equivalence, each performance test on the subject and predicate device have been performed to figure out physical property (e.g. retentive force) with appropriate attachment as intended. Fatigue testing is not considered based on FDA Guidance Document being as proposed abutments is straight type. The subject abutment is intended for straight implantation, and is not received single load, because it used for supporting the overdenture that means load is

	dispersed to the full denture. The test result shows that the performance of subject device supports the substantial equivalence to the predicate device. In conclusion, the subject device is substantially equivalent to the predicate device since the subject and predicate device have in common in indication for use, design, material, function; and the differences are minor and theses have been identified via the performance test the differences do not impact substantial equivalence.

8. Summary of Non-Clinical Testing

The non-clinical testing data which are submitted, referenced, or relied on in this submission support demonstrating substantial equivalence.

Biocompatibility

The biocompatibility evaluation has been performed in accordance with International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process" for the Retentive Ring and Meg-Magnet Abutment.
Cytotoxicity Test – ISO 10993-5
Oral Mucosa Irritation Test – ISO 10993-10
Skin Sensitization Test – ISO 10993-10
Acute Systemic Toxicity Test – ISO 10993-11

The biocompatibility testing for the Meg-Loc Abutment, Meg-Ball Abutment and Metal Cap is leveraged from the AnyOne Internal Implant System (K123988) since these have same material composition, manufacturing process and patient contacting parts as predicate devices.

Modified Surface Treatment

The surface treatment evaluation has been performed in accordance with 'Section 11 of Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutment' to evaluate the TiN coated device:

- Surface Cross section & Coating Thickness Analysis, Component Analysis, Adhesion Grade Analysis

Pyrogen and Endotoxin Test

The subject device will not be labeled as "non-pyrogenic", and the endotoxin testing will be conducted on every batch for the subject device with the testing limit of below 0.5 EU/mL in accordance with the USP 39 <85>.

Sterilization validation

The subject device is supplied in non-sterile state. Sterilization validating testing for steam sterilization by the user has been performed in accordance with ISO 11137 and ISO 17665-1, 2 to verify the sterility assurance level (10^{-6}).

Performance (Physical Properties) Test

The bench tests including retentive force have been performed in accordance with 'Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutment' to evaluate the performance of the subject devices. The retention testing for dental attachment has been conducted as well.

9. Summary of Clinical Testing

No clinical studies are submitted.

10. Conclusion

Based on the information provided in this premarket notification, We, MegaGen Implant Co., Ltd. conclude that the Meg-Ball Attachment System, Meg-Loc Abutment, Meg-Magnet Abutment is substantially equivalent to the predicate device as herein.