November 14, 2019

Megagen Implant Co. Ltd
YouJung Kim
Chief Researcher
45, Secheon-ro 7-gil, Dasa-eup, Dalseong-gun
Daegu, 42921
REPUBLIC OF KOREA

Re: K192347
Trade/Device Name: ST Internal Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: August 14, 2019
Received: August 29, 2019

Dear YouJung 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.
Acting 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)*
K192347

Device Name
ST Internal Implant System

Indications for Use *(Describe)*

The ST Internal Implant System is intended to be surgically placed in the maxillary or mandibular arches 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.

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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510(k) Summary
(K192347)

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

Date: November 13, 2019

1. **Applicant / Submitter**

MegaGen Implant Co., Ltd.
45, Secheon-ro, 7-gil, Dasa-eup, Dalesong-gun,
Daegu, Republic of Korea
Tel: + 82-53-222-2828

2. **Submission Correspondent**

YouJung Kim
MegaGen Implant Co., Ltd.
45, Secheon-ro, 7-gil, Dasa-eup, Dalesong-gun,
Daegu, Republic of Korea
Tel: +82-53-222-2985 Fax: +82-53-289-3420
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3. **Device**

- Trade Name: ST Internal Implant System
- Common Name: Endosseous Dental Implant
- Classification Name: Implant, Endosseous, Root-Form
- Classification Product Code: DZE
- Subsequent Product Code: NHA
- Classification regulation: Class II, 21 CFR 872.3640

4. **Predicate Device:**

- Primary Predicate Device:
  K182448 – AnyRidge Octa 1 Implant System

- Reference Devices:
  K123988 – AnyOne Internal Implant System

5. Description:

The ST Internal Fixture is a substructure of a dental implant system made of CP Ti Grade 4 with the surface treated by SLA method. The abutment is a superstructure of a dental implant system which is attached to the implants made of Ti-6A1-4V ELI with the surface treated by anodizing method(except healing and temporary abutment). The ST Internal Implant System is intended to be placed in the upper or lower jaw to support prosthetic devices, such as artificial teeth, and to restore a patient's chewing function.

The system is consisted of the following components.

Component	Content	
ST Internal Fixture	Description	ST Internal Fixtures are made of titanium. The osseointegrated implant fixtures placed in the anterior or posterior site of maxillary or mandibular jawbone considering bone quality and bone quantity. The dental implants which used in conjunction with other prosthetic restore lost chewing ability, improve appearance.
	Material Composition	CP Ti Grade 4
	Dimension (Diameter &Length)	Ø 3.70 x 8.50, 10.00, 11.50, 13.00, 15.00 mm Ø 4.20 x 7.00, 8.50, 10.00, 11.50, 13.00, 15.00 mm Ø 4.60 x 7.00, 8.50, 10.00, 11.50, 13.00, 15.00 mm Ø 5.10 x 7.00, 8.50, 10.00, 11.50, 13.00, 15.00 mm Ø 6.00 x 7.00, 8.50, 10.00, 11.50,13.00 mm Ø 6.80 x 7.00, 8.50, 10.00, 11.50,13.00 mm
EZ Post Abutment	Description	EZ Post Abutment is used in conjunction with fixture to provide support for cement and screw retained type final prosthesis.
	Material Composition	Ti-6A1-4V ELI
	Dimension (Diameter &Length)	Ø 4.60 x 5.50, 7.00 mm Ø 5.00 x 4.00, 5.50, 7.00 mm Ø 6.00 x 4.00, 5.50, 7.00 mm Ø 7.00 x 5.50 mm
	Angulation	0°
Solid Abutment	Description	Solid Abutment is used in conjunction with fixture to provide support for final prosthesis, and used in cement retained type prosthesis only.
	Material Composition	Ti-6A1-4V ELI
	Dimension (Diameter &Length)	Ø 4.00 x 10.00, 11.00, 11.50, 12.00, 12.50, 13.00, 13.50, 14.00, 14.50, 15.00, 15.50, 16.00, 17.00 mm Ø 4.00 x 10.40, 11.40, 11.90, 12.40, 12.90, 13.40, 13.90, 14.40, 14.90, 15.40, 15.90, 16.40, 17.40 mm Ø 4.60 x 10.00, 11.00, 11.50, 12.00, 12.50, 13.00, 13.50, 14.00, 14.50, 15.00, 15.50, 16.00, 17.00 mm Ø 4.60 x 10.40, 11.40, 11.90, 12.40, 12.90, 13.40, 13.90, 14.40, 14.90, 15.40, 15.90, 16.40, 17.40 mm Ø 5.00 x 10.40, 11.40, 11.90, 12.40, 12.90, 13.40, 13.90, 14.40, 14.90, 15.40, 15.90, 16.40, 17.40 mm Ø 6.00 x 10.40, 11.40, 11.90, 12.40, 12.90, 13.40, 13.90, 14.40, 14.90, 15.40, 15.90, 16.40, 17.40 mm Ø 7.00 x 11.90, 12.90, 13.90, 14.90, 15.90 mm
	Angulation	0°
Angled Abutment	Description	Angled Abutment is used for correcting the prosthetic angulation of implant.
	Material Composition	Ti-6A1-4V ELI
	Dimension (Diameter &Length)	Ø 4.30 x 12.60, 14.60 mm Ø 4.50 x 12.50, 14.50 mm Ø 5.00 x 12.50, 14.50 mm Ø 6.00 x 12.50, 14.50 mm
	Angulation	17°

Milling Abutment	Description	Milling Abutment is used in conjunction with fixture to provide support for cement and screw retained type final prosthesis and used for establishing an adequate safety margin from occlusal line by hand milling of the post part.
	Material Composition	Ti-6A1-4V ELI
	Dimension (Diameter &Length)	Ø 4.00 x 14.50, 14.60 mm Ø 5.00 x 12.00, 14.50 mm Ø 6.00 x 14.50 mm Ø 7.00 x 14.50 mm
	Angulation	0°
Cover Screw	Description	Cover Screw is used for protecting the inner structure of a fixture and the exposed fixture platform after fixture placement.
	Material Composition	Ti-6A1-4V ELI
	Dimension (Diameter &Length)	Ø 3.10 x 5.30mm Ø 3.60 x 5.90mm
	Angulation	0°
Healing Abutment	Description	Healing Abutment helps to form suitable emergence profile during period of gingival healing.
	Material Composition	Ti-6A1-4V ELI
	Dimension (Diameter &Length)	Ø 4.30 x 7.50, 8.50, 8.60, 9.50, 9.60, 10.60, 11.50, 12.60, 13.50, 14.60 mm Ø 4.80 x 7.50, 8.50, 8.60, 9.50, 9.60, 10.60, 11.50, 12.60, 13.50, 14.60 mm Ø 5.30 x 8.60, 9.60, 10.60, 12.60, 14.60 mm Ø 6.30 x 8.60, 9.60, 10.60, 12.60, 14.60 mm Ø 7.30 x 8.60, 9.60, 10.60, 12.60, 14.60 mm
	Angulation	0°
Temporary Abutment	Description	Temporary Abutment is used in conjunction with fixture to provide support for provisional restoration. Temporary Abutment has knurled surface on the top part, which allows for better retention of resin or wax.
	Material Composition	Ti-6A1-4V ELI
	Dimension (Diameter &Length)	Ø 4.00 x 13.60, 15.60 mm Ø 4.50 x 13.50, 15.50 mm
	Angulation	0°
Abutment Screw	Description	Abutment Screw is used for securing the abutment to the endosseous implant.
	Material Composition	Ti-6A1-4V ELI
	Dimension (Diameter &Length)	Ø 2.15 x 10.20 mm Ø 2.35 x 8.40 mm

6. Indication for use:

The ST Internal Implant System is intended to be surgically placed in the maxillary or mandibular arches 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.

7. Basis for Substantial Equivalence

The ST Internal Implant System is substantially equivalent to the predicate device in terms of indication for use, technical characteristics and function. They are made of the same material and have similar design. The size range and design of the subject device slightly differ from the predicate device however it is very minor not affecting substantial equivalence.

In order to demonstrate the difference in design does not raise any new issues in safety and effectiveness, each performance test on the subject and predicate device have been performed to figure out the physical property(e.g. fatigue limit) with combination of the fixture and the angled abutment, in consideration of the worst case according to "ISO 14801:2007" and "Section 8 of Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutment". The test result shows that the subject device is better able to withstand the fatigue and loading.

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.

	Subject Device	**Predicate Device**	**Reference Device**
510(k) Number	Not yet	K182448	K123988
Device Name	ST Internal Fixture	AnyRidge Octa 1 Implant System	AnyOne Internal Implant System
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.
Indications for Use Statement	The ST Internal Implant System is intended to be surgically placed in the maxillary or mandibular arches 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 AnyRidge Octa 1 Implant System is intended to be surgically placed in the maxillary or mandibular arches for the purpose of 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 in the following situations and with the clinical protocols: -Delayed loading. -Immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region.	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.
Appearance			
Material	CP Ti Grade 4	CP Ti Grade 4	CP Ti Grade 4
Sterilization	Gamma sterilization	Gamma sterilization	Gamma sterilization
Diameter(Ø)	3.7, 4.2, 4.6, 5.1, 6.0, 6.8mm	3.6, 4.0, 4.4, 4.7, 4.8, 5.0, 5.5mm	3.9, 4.3, 4.8, 5.3, 5.8, 6.3, 6.8 7.3, 7.8, 8.3 mm
Length (mm)	7.0, 8.5, 10, 11.5, 13, 15mm	7.0, 7.7, 9.2, 10.7, 12.2, 14.2, 17.2mm	7.0, 8.0, 9.5, 11.0, 12.5, 14.5mm
Surface treatment	Sand-blasted, Large grit, Acid-etched (S.L.A)	Sand-blasted, Large grit, Acid-etched (S.L.A)	Sand-blasted, Large grit, Acid-etched (S.L.A)
Implant-to-abutment connection	Hex	Octa	Hex
Feature	- Submerged implant - Tapered body - cutting edge with selftapping - 0.7, 0.8mm thread pitch	- Submerged implant - Tapered body - cutting edge with self-tapping - 0.8mm thread pitch	- Submerged implant - Tapered body - cutting edge with self-tapping - 0.8mm thread pitch

Principle of operation	This product is a tapered body fixture which is inserted in the alveolar bone. It replaces the functions of the missing teeth as a dental implant fixture.	This product is a tapered body fixture which is inserted in the alveolar bone. It replaces the functions of the missing teeth as a dental implant fixture.	This product is a tapered body fixture which is inserted in the alveolar bone. It replaces the functions of the missing teeth as a dental implant fixture.
Shelf Life	5 Years	5 Years	5 Years

Substantial Equivalence Discussion

1. Similarities

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

- Manufacturer, Indication for use, Material, Sterilization Method, Surface treatment, Implant-to-abutment connection, Principle of operation and Shelf life

2. Differences

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

- Diameter, Length and Feature

3. Discussion for difference

- Diameter:
  The diameters of the subject device are slightly different with predicate device however the subject device lies within the range of reference device excepting for diameter 3.7. A diameter 3.7 can be covered with diameter 3.6 included in predicate device.
  There is a minimal difference in the diameter but the substantial equivalence was demonstrated by the fatigue test stated below.
- Feature:
  The subject device has a same feature as a predicate/reference device excluding a thread pitch. A thread pitch(0.7mm) is added in subject device, however there is a just 0.1mm difference in screw pitch between 0.7mm and 0.8mm. It does not cause a matter in substantial equivalence since the size difference is very minor.

∴ In order to demonstrate the differences do not raise an issue in substantial equivalence, each fatigue test on the subject and predicate device have been performed to figure out the physical property(e.g. fatigue limit), with combination of the fixture and the angled abutment, in consideration of the worst case according to “ISO 14801” and “Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutment”. The test result shows that the subject device is better able to withstand the fatigue and loading in spite of the size and feature differences.
In conclusion, the subject device is substantially equivalent to the predicate device since the differences are minor and theses have been identified via the fatigue test the differences do not impact substantial equivalence.

EZ Post Abutment

	Subject Device	Predicate Device	Reference Device
510(k) Number	Not yet	K182448	K123988
Device Name	**EZ Post Abutment** for ST Internal Implant System	**EZ Post Abutment** AnyRidge Octa 1 Implant System	**EZ Post Abutment** for AnyOne Internal Implant System
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.
Indications for Use Statement	The ST Internal Implant System is intended to be surgically placed in the maxillary or mandibular arches 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 AnyRidge Octa 1 Implant System is intended to be surgically placed in the maxillary or mandibular arches for the purpose of 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 in the following situations and with the clinical protocols: -Delayed loading. -Immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region.	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 Ø6.0 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.
Appearance			
Diameter	4.6, 5.0, 6.0, 7.0mm	4.0, 5.0, 6.0, 7.0mm	4.5, 5.5, 6.5 mm
Post Height	4.0, 5.5, 7.0 mm	4.0, 5.5, 7.0 mm	4.0, 5.5mm
Gingival Height	1.0, 2.0, 3.0, 4.0, 5.0mm	0.8, 1.8, 2.8, 3.8, 4.8mm	1.0, 1.5 2.5, 3.5, 4.5, 5.5mm
Connection Interface	Hex, Non-Hex	Octa, non-octa	Hex, Non-Hex
Surface treatment	Anodizing	Anodizing	Anodizing
Sterilization	Non-sterile; intended for terminal sterilization via moist heat(autoclave)	Non-sterile; intended for terminal sterilization via moist heat(autoclave)	Non-sterile; intended for terminal sterilization via moist heat(autoclave)
Angulation	0°	0°	0°
Material	Ti-6A1-4V ELI	Ti-6A1-4V ELI	Ti-6A1-4V ELI
Principle of operation	This product is a superstructure which is connects with the fixtures using the Abutment Screw. It replaces the functions of the missing teeth as a dental abutment.	This product is a superstructure which is connects with the fixtures using the Abutment Screw. It replaces the functions of the missing teeth as a dental abutment.	This product is a superstructure which is connects with the fixtures using the Abutment Screw. It replaces the functions of the missing teeth as a dental abutment.

Substantial Equivalence Discussion

1. **Similarities**

   The subject device has the same characteristic for the following compared to the predicate/reference devices.
   - Manufacturer, Indication for use, Post Height, Connection Interface, Surface Treatment, Sterilization Method, Angulation, Material, and Principle of operation

2. **Differences**

   The subject device has the different characteristic for the following compared to the predicate/reference devices.
   - Diameter, Gingival Height

3. **Discussion for difference**
   - Diameter

     The diameter of the subject device is slightly larger than predicate/reference device by addition of diameter 4.6mm in subject device however it does not cause a matter in substantial equivalence since the subject device lies within the range of the predicate device and the size difference is very minor.
   - Gingival Height:

     The gingival height range of the subject device is slightly different with predicate device however these differences can be covered by reference devices. Also, the variety of the size can be possible to operate more precise treatment to meet each patient's condition and does not cause a matter in substantial equivalence since the size difference is very minor.

Solid Abutment

	Subject Device	Predicate Device
510(k) Number	Not yet	K123988
Device Name	**Solid Abutment** for ST Internal Implant System	**Solid Abutment** for AnyOne Internal Implant System
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.
Indications for Use Statement	The ST Internal Implant System is intended to be surgically placed in the maxillary or mandibular arches 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 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 Ø6.0 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.
Appearance		
Diameter	4.0, 4.6, 5.0, 6.0, 7.0mm	4.0, 4.5, 5.5, 6.5mm
Post Height	4.0, 5.5, 7.0mm	4.0, 5.5, 7.0mm
Gingival Height	1.0, 2.0, 3.0, 4.0, 5.0mm	1.0, 1.5 2.5, 3.5, 4.5, 5.5mm
Connection Interface	Hex	Hex
Surface treatment	Anodizing	Anodizing
Sterilization	Non-sterile; intended for terminal sterilization via moist heat(autoclave)	Non-sterile; intended for terminal sterilization via moist heat(autoclave)
Angulation	0°	0°
Material	Ti-6A1-4V ELI	Ti-6A1-4V ELI
Principle of operation	This product is a superstructure which is connects with the fixtures using the Abutment Screw. It replaces the functions of the missing teeth as a dental abutment.	This product is a superstructure which is connects with the fixtures using the Abutment Screw. It replaces the functions of the missing teeth as a dental abutment.

Substantial Equivalence Discussion

1. **Similarities**

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

- Manufacturer, Indication for use, Post Height, Connection Interface, Surface Treatment, Sterilization Method, Angulation, Material and Principle of operation

2. **Differences**

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

- Diameter and Gingival Height

3. **Discussion for difference**

- Diameter

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

- Gingival Height:

  The gingival height range of the subject device is slightly wider than predicate device by the addition of a gingival height(1.0mm) in subject device however these differences can be covered by reference device. Also, the variety of the size can be possible to operate more precise treatment to meet each patient's condition and does not cause a matter in substantial equivalence since the size difference is very minor.

Angled Abutment

	Subject Device	Predicate Device	Reference Device
510(k) Number	Not yet	K182448	K123988
Device Name	**Angled Abutment** for ST Internal System	**Angled Abutment** for AnyRidge Octa 1 Implant System	**Angled Abutment** for AnyOne Internal Implant System
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.
Indications for Use Statement	The ST Internal Implant System is intended to be surgically placed in the maxillary or mandibular arches 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 AnyRidge Octa 1 Implant System is intended to be surgically placed in the maxillary or mandibular arches for the purpose of 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 in the following situations and with the clinical protocols: -Delayed loading. -Immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region.	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 Ø6.0 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.
Appearance			
Diameter	4.3, 4.5, 5.0, 6.0mm	3.85, 4.2, 5.0, 6.0mm	4.5, 5.5mm
Post Height	8.0mm	7.0m	7.0m
Gingival Height	2.0, 4.0mm	1.8, 2.8, 3.8, 4.8mm	2.5, 4.5mm
Connection Interface	Hex, Hex-E, Non-Hex	Hex, Non-Hex	Hex, Non-Hex
Surface treatment	Anodizing	Anodizing	Anodizing
Sterilization	Non-sterile; intended for terminal sterilization via moist heat(autoclave)	Non-sterile; intended for terminal sterilization via moist heat(autoclave)	Non-sterile; intended for terminal sterilization via moist heat(autoclave)
Angulation	17°	15°, 25°	15°, 25°
Material	Ti-6A1-4V ELI	Ti-6Al-4V ELI	Ti-6Al-4V ELI
Principle of operation	This product is a superstructure which is connects with the fixtures using the Abutment Screw. It replaces the functions of the missing teeth as a dental abutment.	This product is a superstructure which is connects with the fixtures using the Abutment Screw. It replaces the functions of the missing teeth as a dental abutment.	This product is a superstructure which is connects with the fixtures using the Abutment Screw. It replaces the functions of the missing teeth as a dental abutment.

Substantial Equivalence Discussion

1. **Similarities**

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

- Manufacturer, Indication for use, Gingival Height, Surface Treatment, Sterilization Method, Material and Principle of operation

2. **Differences**

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

- Diameter, Post Height, Connection Interface and Angulation

3. **Discussion for difference**

- Diameter:
  The diameter of the subject device is slightly different with predicate/reference devices however it does not cause a matter in substantial equivalence since the subject device lies within the range of the predicate device and the size difference is very minor.
- Post Height:
  The post height is just 1mm longer than predicate/reference devices, however it does not cause a matter in substantial equivalence since the size difference is very minor.
- Connection Interface
  Connection interface can be covered by predicate/reference devices.
  The non-hex type is capable of operating wide range of treatment to meet each patient's condition since the non-hex type is

free from the limit of the angle and direction unlike hex and hex-e type. The multiple predicate devices that have connection interface of non-hex type are already presented in other component comparison charts.

- Angulation

  The angulation of subject device is different with predicate/reference devices however the substantial equivalence have been demonstrated via the fatigue test carried out for the subject & predicate device both. The subject device(angled abutment) has been selected as the representative specimen under the consideration of worst case in accordance with 'ISO 14801' and 'Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutment'. The test result supports that the subject device is substantially equivalent to the predicate devices in spite of the angle differences and not affecting the substantial equivalence.

Milling Abutment

	Subject Device	Predicate Device	Reference Device
510(k) Number	Not yet	K182448	K123988
Device Name	**Milling Abutment** for ST Internal Implant System	**Milling Abutment** for AnyRidge Octa 1 Implant System	**Milling Abutment** for AnyOne Internal Implant System
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.
Indications for Use Statement	The ST Internal Implant System is intended to be surgically placed in the maxillary or mandibular arches 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 AnyRidge Octa 1 Implant System is intended to be surgically placed in the maxillary or mandibular arches for the purpose of 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 in the following situations and with the clinical protocols: -Delayed loading. -Immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region.	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 Ø6.0 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.
Appearance			
Diameter	4.0, 5.0, 6.0, 7.0mm	6.0, 8.0mm	4.0, 4.5, 5.5, 6.5mm
Post Height	9.0, 10.5mm	9.0mm	9.0mm
Gingival Height	1.5, 3.0mm	0.8, 1.8, 2.8, 3.8, 4.8mm	1.5, 2.0, 2.5, 4.0mm
Connection Interface	Hex	Octa, non-octa	Hex, Non-Hex
Surface treatment	Anodizing	Anodizing	Anodizing
Sterilization	Non-sterile; intended for terminal sterilization via moist heat(autoclave)	Non-sterile; intended for terminal sterilization via moist heat(autoclave)	Non-sterile; intended for terminal sterilization via moist heat(autoclave)
Angulation	0°	0°	0°
Material	Ti-6A1-4V ELI	Ti-6A1-4V ELI	Ti-6Al-4V ELI
Principle of operation	This product is a superstructure which is connects with the fixtures using the Abutment Screw. It replaces the functions of the missing teeth as a dental abutment.	This product is a superstructure which is connects with the fixtures using the Abutment Screw. It replaces the functions of the missing teeth as a dental abutment.	This product is a superstructure which is connects with the fixtures using the Abutment Screw. It replaces the functions of the missing teeth as a dental abutment.

Substantial Equivalence Discussion

1. **Similarities**

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

- Manufacturer, Indication for use, Connection Interface, Surface Treatment, Sterilization Method, Angulation, Material and Principle of operation

2. **Differences**

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

- Diameter, Post Height and Gingival Height

3. **Discussion for difference**

- Diameter:
  The diameter of the subject device is slightly different with predicate/reference devices however it does not cause a matter in substantial equivalence since the subject device lies within the combined range of the predicate/reference device and the size difference is very minor.
- Post Height and Gingival Height:
  The post height range of the subject device is slightly different with predicate/reference device by the addition of a post height(10.5mm) in subject device. The variety of the size can be possible to operate more precise treatment to meet each patient's condition. The gingival height range of the subject device is slightly different with predicate/reference device but the subject device lies within the range of the predicate/reference device. Also, these differences do not cause a matter in substantial equivalence since the size difference is very minor.

Cover Screw

	Subject Device	Predicate Device
510(k) Number	Not yet	K182448
Device Name	**Cover Screw** for ST Internal Implant System	**Cover Screw** for AnyRidge Octa 1 Implant System
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.
Indications for Use Statement	The ST Internal Implant System is intended to be surgically placed in the maxillary or mandibular arches 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 AnyRidge Octa 1 Implant System is intended to be surgically placed in the maxillary or mandibular arches for the purpose of 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 in the following situations and with the clinicalprotocols: -Delayed loading. -Immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region.
Appearance		
Diameter	3.1, 3.6mm	3.0, 3.7, 5.0, 6.0mm
Gingival Height	0.4mm	0.5. 1.0mm
Connection Interface	Internal Conical connection	Internal Conical connection
Surface treatment	Anodizing	Anodizing
Sterilization	Gamma sterilization	Gamma sterilization
Angulation	0°	0°
Material	Ti-6A1-4V ELI	Ti-6A1-4V ELI
Principle of operation	Cover Screw is used for protecting the inner structure of a fixture, and exposed fixture platform after fixture placement.	Cover Screw is used for protecting the inner structure of a fixture, and exposed fixture platform after fixture placement.

Substantial Equivalence Discussion

1. **Similarities**
   The subject device has the same characteristic for the following compared to the predicate devices.
   - Manufacturer, Indication for use, Connection Interface, Surface Treatment, Sterilization Method, Angulation, Material and Principle of operation

2. **Differences**
   The subject device has the different characteristic for the following compared to the predicate devices.
   - Diameter and Gingival Height

3. **Discussion for difference**
   - Diameter and Gingival Height
     The diameter range of the subject device is slightly different with predicate devices however it does not cause a matter in substantial equivalence since the subject device lies within the range of the predicate devices. The gingival height range of the subject device is slightly shorter than predicate devices however the variety of the size can be possible to operate more precise treatment to meet each patient's condition. Also, these differences do not cause a matter in substantial equivalence since the size difference is very minor.

Healing Abutment

	Subject Device	Predicate Device	Reference Device
510(k) Number	Not yet	K182448	K123988
Device Name	**Healing Abutment** for ST Internal Implant System	**Healing Abutment** for AnyRidge Octa 1 Implant System	**Healing Abutment** for AnyOne Internal Implant System
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.
Indications for Use Statement	The ST Internal Implant System is intended to be surgically placed in the maxillary or mandibular arches 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 AnyRidge Octa 1 Implant System is intended to be surgically placed in the maxillary or mandibular arches for the purpose of 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 in the following situations and with the clinical protocols: -Delayed loading. -Immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region.	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 Ø6.0 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.
Appearance			
Diameter	4.3, 4.8, 5.3, 6.3, 7.3mm	3.2, 4.2, 5.2, 6.2mm	4.2, 4.7, 5.7, 6.7, 7.7, 8.7, 9.7mm
Gingival Height	3.0, 4.0, 5.0, 7.0, 9.0mm	2.5, 3.5, 4.5, 5.5, 6.5, 7.5, 8.5, 9.5mm	2.3, 2.8, 3.8, 4.8, 5.8, 6.8mm
Connection Interface	Internal Conical connection	Internal Conical connection	Internal Conical connection
Surface treatment	Machined	Anodizing	Machined
Sterilization	Gamma sterilization	Gamma sterilization	Gamma sterilization
Angulation	0°	0°	0°
Material	Ti-6A1-4V ELI	Ti-6A1-4V ELI	Ti-6A1-4V ELI
Principle of operation	The Healing Abutment is fastened into the female screw of dental implant and support the gingival shaping.	The Healing Abutment is fastened into the female screw of dental implant and support the gingival shaping.	The Healing Abutment is fastened into the female screw of dental implant and support the gingival shaping.

Substantial Equivalence Discussion

1. **Similarities**
   The subject device has the same characteristic for the following compared to the predicate/reference devices.
   - Manufacturer, Indication for use, Connection Interface, Surface Treatment, Sterilization Method, Angulation, Material and Principle of operation

2. **Differences**
   The subject device has the different characteristic for the following compared to the predicate/reference devices.
   - Diameter and Gingival Height

3. **Discussion for difference**
   - Diameter and Gingival Height:
     The diameter of the subject device is slightly different with predicate/reference devices however it does not cause a matter in substantial equivalence since the subject device lies within the combined range of the predicate/reference device. The gingival height range of the subject device is slightly different with predicate/reference device but the subject device lies within the range of the predicate device. Also, these differences do not cause a matter in substantial equivalence since the size difference is very minor.

Temporary Abutment

	Subject Device	Predicate Device	Reference Device 2
510(k) Number	Not yet	K182448	K123988
Device Name	**Temporary Abutment** for ST Internal Implant System	**Temporary Abutment** for AnyRidge Octa 1 Implant System	**Temporary Abutment** for AnyOne Internal Implant System
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.
Indications for Use Statement	The ST Internal Implant System is intended to be surgically placed in the maxillary or mandibular arches 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 AnyRidge Octa 1 Implant System is intended to be surgically placed in the maxillary or mandibular arches for the purpose of 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 in the following situations and with the clinical protocols: -Delayed loading. -Immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region.	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 Ø6.0 mm) are dedicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Largerimplants are dedicated for the molar region and are indicated for delayed loading.
Appearance			
Diameter	4.0, 4.5mm	4.0, 5.0mm	4.5mm
Post Height	12mm	10mm	11mm
Gingival Height	1.0, 3.0mm	2.0, 3.0mm	1.0mm
Connection Interface	Hex, Non-Hex	Octa, non-octa	Hex, Non-Hex
Surface treatment	Machined	Anodizing	Machined
Sterilization	Non-sterile; intended for terminal sterilization via moist heat(autoclave)	Non-sterile; intended for terminal sterilization via moist heat(autoclave)	Non-sterile; intended for terminal sterilization via moist heat(autoclave)
Angulation	0°	0°	0°
Material	Ti-6A1-4V ELI	Ti-6A1-4V ELI	Ti-6A1-4V ELI
Principle of operation	Temporary Abutment is used in conjunction with fixture to provide support for provisional restoration.	Temporary Abutment is used in conjunction with fixture to provide support for provisional restoration.	Temporary Abutment is used in conjunction with fixture to provide support for provisional restoration.

Substantial Equivalence Discussion

1. **Similarities**

   The subject device has the same characteristic for the following compared to the predicate/reference devices.
   - Manufacturer, Indication for use, Connection Interface, Surface Treatment, Sterilization Method, Angulation, Material and Principle of operation

2. **Differences**

   The subject device has the different characteristic for the following compared to the predicate/reference devices.
   - Diameter, Post Height and Gingival Height

3. **Discussion for difference**
   - Diameter:

     The diameter of the subject device is slightly smaller than predicate device by addition of diameter 4.5mm in subject device however this difference can be covered by reference device. Also, it does not cause a matter in substantial equivalence since the size difference is very minor.
   - Post Height and Gingival Height:

     The post height is slightly longer than predicate/reference devices, however there is a just 1mm difference between subject and reference device. The gingival height range of subject device is slightly wider than predicate device however one of the gingival heights(1.0mm) in subject device can be covered by reference device. The variety of the size can be possible to operate more precise treatment to meet each patient's condition and these differences do not cause a matter in substantial equivalence since the size difference is very minor.

Abutment Screw

	Subject Device	Predicate Device	Predicate Device
510(k) Number	Not yet	K182448	K123988
Device Name	**Abutment Screw** for ST Internal Implant System	**Abutment Screw** for AnyRidge Octa 1 Implant System	**Abutment Screw** for AnyOne Internal Implant System
Manufacturer	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.	MegaGen Implant Co., Ltd.
Indications for Use Statement	The ST Internal Implant System is intended to be surgically placed in the maxillary or mandibular arches 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 AnyRidge Octa 1 Implant System is intended to be surgically placed in the maxillary or mandibular arches for the purpose of 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 in the following situations and with the clinical protocols: -Delayed loading. -Immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region.	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 Ø6.0 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.
Appearance			
Diameter	2.15, 2.35mm	2.2mm	2.3mm
Total Height	8.4, 10.2mm	7.9	9.9mm
Connection Interface	Internal Conical connection	Internal Conical connection	Internal Conical connection
Surface treatment	Anodizing	Machined	Machined
Sterilization	Non-sterile; intended for terminal sterilization via moist heat(autoclave)	Non-sterile; intended for terminal sterilization via moist heat(autoclave)	Non-sterile; intended for terminal sterilization via moist heat(autoclave)
Material	Ti-6A1-4V ELI	Ti-6A1-4V ELI	Ti-6A1-4V ELI
Principle of operation	Abutment screw is used for securing the abutment to the endosseous implant.	Abutment screw is used for securing the abutment to the endosseous implant.	Abutment screw is used for securing the abutment to the endosseous implant.

Substantial Equivalence Discussion

1. **Similarities**

   The subject device has the same characteristic for the following compared to the predicate devices.
   - Manufacturer, Indication for use, Connection Interface, Sterilization Method, Angulation, Material and Principle of operation

2. **Differences**

   The subject device has the different characteristic for the following compared to the predicate devices.
   - Diameter, Total Height and Surface treatment

3. **Discussion for difference**
   - Diameter and Total Height:
     The diameter and total height range of the subject device is slightly different with predicate/reference device however it does not cause a matter in substantial equivalence since the size difference is very minor.
   - Surface Treatment:
     The other difference is in surface treatment but we already presented multiple predicate/reference devices for anodizing in the other component comparison charts.

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". The additional biocompatibility testing is not required since the ST Internal Implant System has same material composition, manufacturing process and patient contacting parts as predicate device, AnyRidge Octa 1 Implant System (K182448) for fixtures(ASTM F67) and abutments(ASTM F136).

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 Abutments - Guidance for Industry and FDA Staff'.
The ST Internal Implant System has same surface treatment and manufacturing process as predicate device, AnyRidge Octa 1 Implant System(K182448) for the surface treatment of S.L.A(Fixtures).

Pyrogen and Endotoxin Test
The endotoxin testing will be conducted on every batch for the subject device in accordance with 'Guidance for Industry Pyrogen and Endotoxins Testing: Questions and Answers'.

Sterilization validating and Shelf Life
Sterilization validating testing has been performed in accordance with ISO 11137 and ISO 17665-1, 2 to verify the sterility assurance level (10-6). The tests to validate the shelf life of the device through the proposed shelf life were conducted using the accelerated aging method in accordance to ASTM F1980 and the test results validated 5 year shelf life.

Also, the following guidance documents were referred to:

- Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile.
- Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling

Performance (Physical Properties) Test
The following bench tests have been performed in accordance with "ISO 14801" and "Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutment" to evaluate the performance of the subject devices and the test results met the pre-set criteria.

- Static compression-strength test
- Fatigue test

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 ST Internal Implant System is substantially equivalent to the predicate device as herein.