October 6, 2017

ACHIMHAI Medical Corporation
% Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Inc.
800 Roosevelt, Suite 417
Irvine, California 92620

Re: K170394
Trade/Device Name: Kisses Mini
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: September 4, 2017
Received: September 7, 2017

Dear Priscilla Chung:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Andrew I. Steen -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K170394

Device Name
Kisses Mini

Indications for Use *(Describe)*

The Kisses Mini is indicated for use in partially or fully edentulous mandibles and maxilla, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. The Kisses Mini is for single and two stage surgical procedures. It is for delayed loading.

The intended use of the 3.2 mm Internal Hex fixtures is limited to the replacement of maxillary lateral incisors and mandibular incisors.

The intended use of the single-piece post type fixture is limited to replacement of mandibular central and lateral incisors.

The ball-type single-piece implant is intended for stabilization and retention of overdentures.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

(K170394)

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

Date: 10/06/2017

1. Submitter

ACHIMHAI Medical Corporation
28, Namyang-ro, 930beon-gil, Namyang-eup
Hwaseong-si, Gyeonggido, Republic of Korea, 18255

2. U.S Agent/Contact Person

Priscilla Chung
LK Consulting Group USA, Inc.
800 Roosevelt Ste 417, Irvine CA 92620
Phone: 714.202.5789 Fax: 714-409-3357
Email: juhee.c@lkconsultinggroup.com

3. Device

- Trade Name: Kisses Mini
- Common Name: Dental Implant System
- Classification Name: Endosseous Dental Implant System
- Product Code: DZE, NHA
- Classification regulation: 21CFR872.3640

4. Predicate Device:

- **Primary Predicate Device:**
  MiNi Internal Implant System (K150537) by MegaGen Implant Co., Ltd.
  S-MiNi Implant System (K112540) by Neobiotech Co., Ltd.
- **Reference Predicate Device:**
  Biogenesis Implant System – Kisses (K142813) by Achimhai Medical Corporation

5. Description:

KJ Mini offers three different types of implants: 2-Piece Type, Post Type, and Ball Type.

The 2-piece type fixture is a substructure of a dental implant system to replace a single tooth, and the lost root of edentulous patients. It consists of the hex part to be coupled to the superstructure, the single thread part to be fixed to the bone, and the cutting edge part with the self-tapping function. It offers single hex type and double hex type.

- 3.2mm Dia. x 8mm L
- 3.2mm Dia. x 9.5mm L
- 3.2mm Dia. x 11mm L
- 3.2mm Dia. x 12.5mm L
- 3.2mm Dia. x 14.5mm L

The post type fixture is a substructure of a dental implant system to replace a single tooth, and the lost root of edentulous patients.

- 2.8mm Dia. x 8mm L
- 2.8mm Dia. x 9.5mm L
- 2.8mm Dia. x 11mm L
- 2.8mm Dia. x 12.5mm L
- 2.8mm Dia. x 14.5mm L
- 3mm Dia. x 8mm L
- 3mm Dia. x 9.5mm L
- 3mm Dia. x 11mm L
- 3mm Dia. x 12.5mm L
- 3mm Dia. x 14.5mm L

The ball type fixture is a substructure of a dental implant system to replace a single tooth, and the lost root of edentulous patients.

- 2.8mm Dia. x 8mm L
- 2.8mm Dia. x 9.5mm L
- 2.8mm Dia. x 11mm L
- 2.8mm Dia. x 12.5mm L
- 2.8mm Dia. x 14.5mm L
- 3mm Dia. x 8mm L
- 3mm Dia. x 9.5mm L
- 3mm Dia. x 11mm L
- 3mm Dia. x 12.5mm L
- 3mm Dia. x 14.5mm L

6. Indication for use:

The Kisses Mini is indicated for use in partially or fully edentulous mandibles and maxilla, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. The Kisses Mini is for single and two stage surgical procedures. It is for delayed loading.

The intended use of the 3.2 mm Internal Hex fixtures is limited to the replacement of

maxillary lateral incisors and mandibular incisors.

The intended use of the single-piece post type fixture is limited to replacement of mandibular central and lateral incisors.

The ball-type single-piece implant is intended for stabilization and retention of overdentures.

7. Basis for Substantial Equivalence

7.1. Fixture

Internal Hex Type

	Subject Device	Primary Predicate Device	Reference Predicate Device
510(K) Number	-	K150537	K142813
Device Name	Kisses Mini	MiNi Internal Implant System	Biogenesis Implant System - Kisses
Manufacturer	Achimhai Medical Corporation	MegaGen Implant Co., Ltd.	Achimhai Medical Corporation (Note: Our company name has changed from Biogenesis to Achimhai.)
Type	Internal hex	Internal hex	Internal hex
Design & Size Range	 Diameter: 3.2 mm Length: 8 – 14.5 mm	 Diameter: 3.0 – 3.4 mm Length: 8-14.5 mm	 Diameter: 3.5 – 5.5 mm Length: 7-15 mm
Indications for Use	The Kisses Mini is indicated for use in partially or fully edentulous mandibles and maxilla, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. The Kisses Mini is for single and two stage surgical procedures. It is for delayed loading. The intended use of the 3.2 mm Internal Hex fixtures is limited to the replacement of maxillary lateral incisors and mandibular incisors. The intended use of the single-piece post type fixture is limited to replacement of mandibular central and lateral incisors.	The MiNi Internal Implant System is intended for two stage surgical procedures in the following situations and with the following clinical protocols: • The intended use for the 3.0 mm diameter MiNi implant is limited to the replacement of maxillary lateral incisors and mandibular incisors. • Immediate placement in extraction sites and in situations with a partially or completely healed alveolar ridge. • It is intended for delayed loading.	The Biogenesis Implant System –Kisses is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. The Biogenesis Implant System – Kisses is for single and two stage surgical procedures. It is for delayed loading.

	The ball-type single-piece implant is intended for stabilization and retention of overdentures.		
Principle of Operation	The device is a substructure of a dental implant system to replace a single tooth and the lost root of edentulous patients. It consists of the hex part to be coupled to the superstructure, the single thread part to be fixed to the bone, and the cutting edge part with the self-tapping function.	The device is a substructure of a dental implant system to replace a single tooth and the lost root of edentulous patients. It consists of the hex part to be coupled to the superstructure, the single thread part to be fixed to the bone, and the cutting edge part with the self-tapping function.	The device is a substructure of a dental implant system to replace a single tooth and the lost root of edentulous patients. It consists of the hex part to be coupled to the superstructure, the single thread part to be fixed to the bone, and the cutting edge part with the self-tapping function.
Material Composition	Ti Gr.4	Ti Gr.4	Ti Gr.4
Surface Treatment	SLA Treatment	SLA Treatment	SLA Treatment
Sterile	Yes	Yes	Yes
Sterilization Method	Gamma	Gamma	Gamma

Substantial Equivalence Discussion

Kisses Mini Internal hex type fixture is substantially equivalent to the predicate devices in terms of intended use and technical characteristics. They have similar design that all the devices are two piece type fixtures with thread part to be fixed to the bone. They are made of the same material and all have cutting edge part for self-tapping function. The size range of the primary predicate device encompasses the size range of the subject device.
There are slight differences in design such as thread sizes but it is very minor not affecting the substantial equivalence. Also, the Kisses Mini indications for use differ from the predicate devices in some languages for specific types and size, however, these differences do not raise new concerns because limiting the use of each type is a more conservative surgical approach.

Post Type

	Subject Device	Primary Predicate Device
510(K) Number	N / A	K112540
Device Name	Kisses Mini	S-MiNi Implant System
Manufacturer	Achimhai Medical Corporation	Neobiotech Co., Ltd.
Type	Post	Post
Design & Size Range	 Diameter: 2.8 - 3.0 mm Length: 8 – 14.5 mm Cuff: 2.5 – 4.0 mm Post: 8.0 mm	 Diameter: 2.0 – 3.5 mm Length: 7-15 mm Cuff: 2.0 mm Post: 10.0 mm
Intended Use	The Kisses Mini is indicated for use in partially or fully edentulous mandibles and maxilla, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or	The S-MiNi Implant System is intended to use in the treatment of missing mandibular central and lateral incisors to support prosthetic device, such as artificial teeth, in order to restore chewing function partially edentulous.

	intermediate abutment support for fixed bridgework. The Kisses Mini is for single and two stage surgical procedures. It is for delayed loading. The intended use of the 3.2 mm Internal Hex fixtures is limited to the replacement of maxillary lateral incisors and mandibular incisors. The intended use of the single-piece post type fixture is limited to replacement of mandibular central and lateral incisors. The ball-type single-piece implant is intended for stabilization and retention of overdentures.	
Principle of Operation	The device is a substructure of a dental implant system to replace a single tooth and the lost root of edentulous patients. It consists of the single thread part and the post part; the single thread part to be fixed to the bone, and the cutting edge part with the self-tapping function.	The device is a substructure of a dental implant system to replace a single tooth and the lost root of edentulous patients. It consists of the single thread part and the post part; the single thread part to be fixed to the bone, and the cutting edge part with the self-tapping function.
Material Composition	Ti Gr.4	Ti Gr.4
Surface Treatment	SLA Treatment	RBM Treatment
Sterile	Yes	Yes
Sterilization Method	Gamma	Gamma

Substantial Equivalence Discussion

Kisses Mini Post type Implant is substantially equivalent to the predicate devices in terms of intended use and technical characteristics. The design is very similar that the both devices are one body type which a fixture and an abutment are combined. They are made of the same material and all have cutting edge part for self-tapping function. The size range of the predicate device encompasses the size range of the subject device.
The difference is in cuff size that the subject device cuff is longer than the predicate device. However, this difference does not affect substantial equivalence.
Another difference is in surface treatment that the subject device employs SLA and the predicate device employs RBM. For the subject deice, surface morphology, surface roughness Analysis, and FT-IR Analysis were performed to evaluate its characteristics, and the test results support it does not affect substantial equivalence.
Also, the Kisses Mini indications for use differ from the predicate devices in some languages for specific types and size, however, these differences do not raise new concerns because limiting the use of each type is a more conservative surgical approach.

Ball Type

	Subject Device	Primary Predicate Device
510(K) Number	N / A	K112540
Device Name	Kisses Mini	S-MiNi Implant System
Manufacturer	Achimhai Medical Corporation	Neobiotech Co., Ltd.
Type	Ball	Ball

Design & Size Range	 Diameter: 2.8 – 3.0 mm Length: 8 – 14.5 mm Cuff: 2.0 – 4.0 mm	 Diameter: 2.0 – 3.5 mm Length: 7 - 15 mm Cuff: 3.0 – 4.0 mm
Intended Use	The Kisses Mini is indicated for use in partially or fully edentulous mandibles and maxilla, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. The Kisses Mini is for single and two stage surgical procedures. It is for delayed loading. The intended use of the 3.2 mm Internal Hex fixtures is limited to the replacement of maxillary lateral incisors and mandibular incisors. The intended use of the single-piece post type fixture is limited to replacement of mandibular central and lateral incisors. The ball-type single-piece implant is intended for stabilization and retention of overdentures.	The S-MiNi Implant System is intended to be place in the bone of the upper or lower jaw arches to provide support the prosthetic devices to restore the patient's chewing function, including the denture stabilization. S-MiNi Implant System is intended for single use only
Principle of Operation	The device is a substructure of a dental implant system to replace a single tooth and the lost root of edentulous patients. It consists of the single thread part and the ball part; the single thread part to be fixed to the bone, the cutting edge part with the self-tapping function, and the ball part for detachable denture.	The device is a substructure of a dental implant system to replace a single tooth and the lost root of edentulous patients. It consists of the single thread part and the ball part; the single thread part to be fixed to the bone, the cutting edge part with the self-tapping function, and the ball part for detachable denture.
Material Composition	Ti Gr.4	Ti Gr.4
Surface Treatment	SLA Treatment	RBM Treatment
Sterile	Yes	Yes
Sterilization Method	Gamma	Gamma

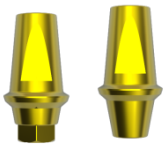
Substantial Equivalence Discussion

Kisses Mini Ball type Implant is substantially equivalent to the predicate devices in terms of intended use and technical characteristics. The design is also similar that the both devices have a ball-type structure for the connection of the O-ring attachment. They are made of the same material and all have cutting edge part for self-tapping function. The size range of the predicate device encompasses the size range of the subject device.
There is slight difference in design such as cuff design but it is very minor not affecting substantial equivalence.
Another difference is in surface treatment that the subject device employs SLA and the predicate device employs RBM. For the subject deice, surface morphology, surface roughness Analysis, and FT-IR Analysis were performed to evaluate its characteristics, and the test results support it does not affect substantial equivalence.

Also, the Kisses Mini indications for use differ from the predicate devices in some languages for specific types and size, however, these differences do not raise new concerns because limiting the use of each type is a more conservative surgical approach.

7.2. Abutment

	Subject Device	Primary Predicate Device	Reference Predicate Device
510(K) Number	-	K150537	K142813
Device Name	Kisses Mini	MiNi Internal Implant System	Biogenesis Implant System - Kisses
Manufacturer	Achimhai Medical Corporation	MegaGen Implant Co., Ltd.	Achimhai Medical Corporation (Note: Our company name has changed from Biogenesis to Achimhai.)
Type	Internal	Internal	Internal hex
Indications for Use	The Kisses Mini is indicated for use in partially or fully edentulous mandibles and maxilla, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. The Kisses Mini is for single and two stage surgical procedures. It is for delayed loading. The intended use of the 3.2 mm Internal Hex fixtures is limited to the replacement of maxillary lateral incisors and mandibular incisors. The intended use of the single-piece post type fixture is limited to replacement of mandibular central and lateral incisors. The ball-type single-piece implant is intended for stabilization and retention of overdentures.	The MiNi Internal Implant System is intended for two stage surgical procedures in the following situations and with the following clinical protocols: • The intended use for the 3.0 mm diameter MiNi implant is limited to the replacement of maxillary lateral incisors and mandibular incisors. • Immediate placement in extraction sites and in situations with a partially or completely healed alveolar ridge. • It is intended for delayed loading.	The Biogenesis Implant System –Kisses is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. The Biogenesis Implant System – Kisses is for single and two stage surgical procedures. It is for delayed loading.
Principle of Operation	The abutments are to be coupled to the fixtures to make temporary or final prosthesis.	The abutments are to be coupled to the fixtures to make temporary or final prosthesis.	The abutments are to be coupled to the fixtures to make temporary or final prosthesis.
Abutment 1– Duplex Abutment			

<Duplex Abutment> Design & Size Range	 Hex Diameter: 3.5mm Post Height : 5.5mm-7.0mm Gingival Height: 1mm - 4.5mm	 Hex Diameter: 3.5mm Post Height : 5.0mm-9.0mm Gingival Height: 1mm - 4.5mm	 Hex & Non-Hex Diameter: 4.5mm - 6.5mm Post Height : 5.5mm Gingival Height: 1mm - 5.5mm
Intended Use	Cement retained restoration	Cement retained restoration	Cement retained restoration
Material Composition	Ti Gr.4	Ti Gr.4	Ti Gr.4
Surface Treatment	Anodizing coloring – Gold color (Entire Body)	Anodizing coloring – Gold color(Entire Body)	Anodizing coloring – Gold color (Entire Body)
Sterile	No	No	No

Substantial Equivalence Discussion

The subject Duplex Abutment is substantially equivalent to the predicate devices in terms of intended use and technical characteristics. They are made of the same material and have similar design that all have the hex type. The size range of the predicate devices encompasses the size range of the subject device. All the devices have anodizing coloring in the entire body.
There might slight differences in design but it is very minor not affecting substantial equivalence.

Abutment 2– Simplex Abutment			
<Simplex Abutment> Design & Size Range	 Diameter: 3.5mm Post Height : 5.5mm-7.0mm Gingival Height: 1mm - 4.5mm	 Diameter: 3.5mm Post Height : 5.0mm-9mm Gingival Height: 1mm - 4.5mm	 Diameter: 4.5mm - 6.5mm Post Height : 5.5mm Gingival Height: 1mm - 5.5mm
Intended Use	Cement retained restoration	Cement retained restoration	Cement retained restoration
Material Composition	Ti 6Al 4V ELI, Gr.23	Ti 6Al 4V ELI, Gr.23	Ti 6Al 4V ELI, Gr.23
Surface Treatment	Anodizing coloring – Gold color(Entire Body)	Anodizing coloring – Gold color(Entire Body)	Anodizing coloring – Gold color(Entire Body)
Sterile	No	No	No

Substantial Equivalence Discussion

The subject Simplex Abutment is substantially equivalent to the predicate devices in terms of intended use and technical characteristics. They are made of the same material and have similar design that all are one-piece type abutments. The size range of the predicate devices encompasses the size range of the subject device. All the devices have anodizing coloring in the entire body.
There might be slight differences in design but it is very minor not affecting substantial equivalence.

Abutment 3–Angled Abutment

<Angled Abutment> Design & Size Range	 Hex& Non-Hex Diameter: 3.5mm Gingival Height: 2mm - 4mm Angle: 15° - 25°	 Hex& Non-Hex Diameter: 3.5mm Gingival Height: 2.5mm – 4.5mm Angle: 15°	
Intended Use	Cement retained restoration	Cement retained restoration	
Material Composition	Ti Gr.4	Ti Gr.4	
Surface Treatment	Anodizing coloring – Gold color(Entire Body)	Anodizing coloring – Gold color(Entire Body)	
Sterile	No	No	

Substantial Equivalence Discussion

The subject Angled Abutment is substantially equivalent to the predicate devices in terms of intended use and technical characteristics. They are made of the same material and have similar design. The size range of the predicate devices encompasses the size range of the subject device. All the devices have anodizing coloring in the entire body.
There might be slight differences in design but it is very minor not affecting substantial equivalence.
The major difference is that subject device has a model with 25° angle which is greater than the subject device, however, the test result of the fatigue test supported substantial equivalence.

Abutment 4– Temporary Abutment			
<Temporary Abutment> Design & Size Range	 Hex Diameter: 3.5mm Gingival Height: 1mm	 Hex Diameter: 3.0mm Gingival Height: 1mm	 Hex & Non-Hex Diameter: 4.5mm Gingival Height: 1mm
Intended Use	To manufacture temporary prostheses	To manufacture temporary prostheses	To manufacture temporary prostheses
Material Composition	Ti Gr.4	Ti Gr.4	Ti Gr.4
Surface Treatment	No	No	No
Sterile	No	No	No

Substantial Equivalence Discussion

The subject Temporary Abutment is substantially equivalent to the predicate devices in terms of intended use and technical characteristics. They are made of the same material. The design is the same as the reference predicate device. The size range of the predicate devices encompasses the size range of the subject device.

Abutment 5– Ball Cap & O-ring			
<Ball Cap & O-ring> Design & Size Range	 Diameter: 5.0mm Height: 3.85mm		 Diameter: 5.0mm Gingival Height: 3.85mm

	 Outer Diameter: 4.5mm Inner Diameter: 1.5mm		 Outer Diameter: 4.5mm Inner Diameter: 1.5mm
Intended Use	Denture retained restoration		Denture retained restoration
Material Composition Housing O-ring	 Ti 6Al 4V ELI, Gr.23 Silicon(USP Class VI grade)		 Ti 6Al 4V ELI, Gr.23 Silicon(USP Class VI grade)
Surface Treatment	No		No
Sterile	No		No
Substantial Equivalence Discussion The subject ball cap and O-ring are the same as the predicate device in intended use, technological characteristics, size, design, dimensions and material. There is no difference.			

7.3. Screws

	Subject Device	Predicate Device
510(K) Number	N / A	K150537
Device Name	Kisses Mini	MiNi Internal Implant System
Manufacturer	Achimhai Medical Corporation	MegaGen Implant Co., Ltd.
Indications for Use	The Kisses Mini is indicated for use in partially or fully edentulous mandibles and maxilla, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. The Kisses Mini is for single and two stage surgical procedures. It is for delayed loading. The intended use of the 3.2 mm Internal Hex fixtures is limited to the replacement of maxillary lateral incisors and mandibular incisors. The intended use of the single-piece post type fixture is limited to replacement of mandibular central and lateral incisors. The ball-type single-piece implant is intended for stabilization and retention of overdentures.	The MiNi Internal Implant System is intended for two stage surgical procedures in the following situations and with the following clinical protocols: • The intended use for the3.0 mm diameter MiNi implant is limited to the replacement of maxillary lateral incisors and mandibular incisors. • Immediate placement in extraction sites and in situations with a partially or completely healed alveolar ridge. • It is intended for delayed loading.
Principle of Operation	▪ Abutment Screw is to connect the abutment to the fixture. ▪ Cover Screw is to prevent tissue and bone to grow inside the implant. ▪ Healing Screw is to help the soft tissue of gum naturally formed.	▪ Abutment Screw is to connect the abutment to the fixture. ▪ Cover Screw is to prevent tissue and bone to grow inside the implant. ▪ Healing Screw is to help the soft tissue of gum naturally formed.
Abutment Screw		

<Abutment Screw> Design & Size Range	 Tap: M1.4	 Tap: M1.4
Material Composition	Ti 6Al 4V ELI, Gr.23	Ti 6Al 4V ELI, Gr.23
Surface Treatment	Anodizing coloring(Entire Body)	No
Sterile	No	No

Substantial Equivalence Discussion

The subject abutment screw is substantially equivalent to the predicate device in intended use, technological characteristics, size, design, and material. The difference is that the subject screw has anodizing color but this coloring does not raise a questions in safety and effectiveness.

Cover Screw		
<Cover Screw> Design & Size Range	 Tap: M1.4	 Tap: M1.4
Material Composition	Ti 6Al 4V ELI, Gr.23	Ti 6Al 4V ELI, Gr.23
Surface Treatment	Anodizing coloring(Entire Body)	Anodizing coloring(Entire Body)
Sterile	Yes	Yes
Sterilization Method	Gamma	Gamma

Substantial Equivalence Discussion

The subject cover screw is substantially equivalent to the predicate device in intended use, technological characteristics, size, design, and material. The anodizing color is different but the coloring does not raise a questions in safety and effectiveness.

Healing Screw		
<Healing Screw> Design & Size Range	 Diameter: 3.0 mm – 3.5mm Cuff: 1.0mm - 4.5mm Tap: M1.4	 Diameter: 3.0 mm – 3.5mm Cuff: 1.0mm - 4.5mm Tap: M1.4
Material Composition	Ti 6Al 4V ELI, Gr.23	Ti 6Al 4V ELI, Gr.23
Surface Treatment	No	No
Sterile	Yes	Yes
Sterilization Method	Gamma	Gamma

Substantial Equivalence Discussion

The subject healing screw is substantially equivalent to the predicate device in intended use, technological characteristics, size, design, and material. The anodizing color is different but the coloring does not raise a questions in safety and effectiveness.

Substantial Equivalence Discussion for the Whole System

Kisses Mini is substantially equivalent to the predicate devices in terms of intended use and technical characteristics. They are made of the same material and have similar design. The size range of the predicate device encompasses the size range of the subject device. There are slight differences in design, however, it is very minor not affecting substantial equivalence. The Kisses Mini indications for use differ from the predicate devices in some languages for specific types and size, however, these differences do not raise new concerns because limiting the use of each type is a more conservative surgical approach.
Another difference is in surface treatment for fixture that the subject device employs SLA and some of the predicate device employs RBM. For the subject deice, surface morphology, surface roughness analysis, and FT-IR analysis were performed to evaluate its characteristics, and the test results support it does not affect substantial equivalence.
Major difference in abutment is that it has a model with 25° angle which is greater than the subject device, however, the test result of the fatigue test supported substantial equivalence.
Based on the information and test results provided in submission, we conclude that the subject device is substantially equivalent to the predicate devices.

8. Non-Clinical Testing

- Sterilization validating testing has been performed in accordance with ISO 11137 for gamma sterilization and ISO 17665-1 and ISO 17665-2 for steam sterilization.
- Three year of shelf life has been validated through accelerating testing.
- Surface Morphology, Surface Roughness Analysis, and FT-IR Analysis were performed to evaluate the fixture surface characteristics after SLA treatment.
- Other Performance tests: Visual inspection, Dimension, Packing inspection, Sterility, Adaption accuracy, Marginal adaptation, Compressive strength, Fatigue, Rotational sheer strength, Screw loosening torque tests
- The endotoxin testing will be conducted on every batch for the subject device. The USP <85> test method will be used to evaluate pyrogen limit specifications for the subject device. The testing limit is below 0.5 EU/mL. We referenced the USP 39 <85> Bacterial Endotoxin Test on the endotoxin limit which is 0.5 EU/mL.

9. Conclusion

The subject devices and the predicate device have the same intended use and have the same technological characteristics.

Overall, the Kisses Mini has the following similarities to the predicate device:

* have the same intended use,
* use the same operating principle,
* incorporate the same design,
* incorporate the same material and the sterilization method.

Based on the similarities, we conclude that the Kisses Mini is substantially equivalent to the predicate devices.