Guilin FiTeeth Medical Instrument Co., Ltd.
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, 200120
CHINA

October 13, 2022

Re: K212702
Trade/Device Name: IM/ST Fixture System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: September 15, 2022
Received: September 15, 2022

Dear Diana Hong:

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,

Andrew I. Steen
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)* K212702

Device Name
IM/ST Fixture System

Indications for Use *(Describe)*
The IM/ST Fixture System 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 final or temporary abutment support for fixed bridgework. It is intended 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.**

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:

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# 510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

The assigned 510(k) Number: K212702

1. Date of Preparation: 10/13/2022

2. Sponsor Identification

**Guilin FiTeeth medical instrument Co., Ltd.**
Southeast side of Renmin road extension line, Yangtang industrial park, Lingui district, Guilin city, Guangxi zhuang autonomous region

Establishment Registration Number: Not yet registered

Contact Person: Jun Zhou
Position: Project Manager
Tel: +86-773-2350558
Fax: +86-773-5822450
Email: 364883667@qq.com

3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Ying Xu (Alternative Contact Person)

**Mid-Link Consulting Co., Ltd**
P.O. Box 120-119, Shanghai, 200120, China

Tel: +86-21-22815850
Fax: 360-925-3199
Email: info@mid-link.net

4. Identification of Proposed Device

Trade Name: IM/ST Fixture System
Common Name: Dental Implant

Regulatory Information
Classification Name: Endosseous Dental Implant
Classification: II
Product Code: DZE, NHA
Regulation Number: 21 CFR 872.3640
Review Panel: Dental

Indications for Use

The IM/ST Fixture System 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 final or temporary abutment support for fixed bridgework. It is intended for delayed loading.

Device Description

The proposed device, IM/ST Fixture System, 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 final or temporary abutment support for fixed bridgework. It is intended for delayed loading.

Implant system contain dental implant and abutment. The dental implant system has two system, IM Implant System and ST Implant System, both of which are divided into mini implant and regular implant. IM Implant and ST Implant have different designs for the external thread section. The external thread part of IM implant is composed of conical shape, double thread and spiral groove, while The external thread part of ST implant is composed of conical shape, single thread, neck micro thread and cutting groove. Both IM implant and ST implant are available in diameters of 3.75, 4.2, 4.6 and 5.05mm and lengths of 7, 8.5, 10, 11.5, 13 and 15mm, and both are bone level. The “mini” and “regular” differ in size, but abutments are cross-compatible with both IM and ST implant types, and the abutment is attached to the implant by abutment screw and fastened to the implant. The material of abutment screw is Titanium Alloy (Ti-6Al-4V, ASTM F136).

The implants are bone level. The implants were made of Pure Titanium Grade 4 and underwent sandblasting and acid etching process. Modified surface testing (SEM/EDS) for blasted/etched surfaces was conducted to demonstrate removal of particles and chemicals from implant surface.

Abutment can be divided into healing abutment, straight abutment, angle abutment, multi-abutment, multi-angled abutment and temporary abutment. And it is divided into mini abutment and regular abutment. In addition, abutment also has three types of cylinder, straight cylinder, angled cylinder and temporary cylinder.

5. Identification of Primary Predicate Device

510(k) Number: K121995
Product Name: TS FIXTURE SYSTEM
Manufacturer: OSSTEM IMPLANT CO.,LTD

6. Identification of Reference Devices

Reference Device 1
510(k) Number: K192436
Device Name: Healing Abutments and Cover Screws
Manufacturer: Dentium Co., Ltd.

Reference Device 2
510(k) Number: K161689
Device Name: OSSTEM Implant System - Abutment
Manufacturer: OSSTEM IMPLANT Co., Ltd.

Reference Device 3
510(k) Number: K182091
Device Name: Osstem Abutment System
Manufacturer: OSSTEM IMPLANT CO., LTD

Reference Device 4
510(k) Number: K120847
Device Name: ET/SS IMPLANT SYSTEM
Manufacturer: OSSTEM IMPLANT CO., LTD

Reference Device 5
510(k) Number: K152509
Device Name: CAMLOG and CONELOG Abutments for Screw-retained Restorations (ASR)
Manufacturer: ALTATEC GMBH

7. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was compared to the predicate device and reference device. The test results demonstrated that the proposed device complies with the following standards:

- ISO 10993-1:2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- ISO 14801:2016 Dentistry-Implants-Dynamic fatigue test for endosseous dental implants
- USP <85> Bacterial Endotoxin Test
- ASTM F136-13, Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications
- ASTM F67-13 (Reapproved 2017), Standard Specification for Unalloyed Titanium for Surgical Implant Applications
- ISO 17665-1:2006 Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
- ISO 17665-2:2009 Sterilization of health care products - Moist heat - Part 2: Guidance on the application of ISO 17665-1
- ISO 11137-2:2013 Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose
- ISO 11137-1:2006 Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices [Including: Amendment 1 (2013) and Amendment 2 (2018)]
- ASTM F1980:2016 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

"Non-clinical worst-case MRI review was performed to evaluate the IM/ST Fixture System devices in the MRI environment using scientific rationale and published literature (e.g., Woods, Terry O., Jana G. Delfino, and Sunder Rajan. "Assessment of Magnetically Induced Displacement Force and Torque on Metal Alloys Used in Medical Devices." Journal of Testing and Evaluation 49.2 (2019): 783-795), based on the entire system including all variations (all compatible implant bodies, dental abutments, and fixation screws) and material composition. Rationale addressed parameters per the FDA guidance "Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment," including magnetically induced displacement force and torque.

8. Clinical Test Conclusion

No clinical study is included in this submission.

9. Summary of Technological characteristics

Table 1 Characteristic Comparison for Implant

| Item | Proposed Device | Predicate Device K121995 | Remark |
|---|---|---|---|
| Device Class | II | II | Similar |
| Product Code | DZE | DZE | Similar |
| Regulation Number | 872.3640 | 872.3640 | Similar |
| Indications for Use | The IM/ST Fixture System 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 final or temporary abutment support for fixed bridgework. It is intended for delayed loading. | The TS Fixture System 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 final or temporary abutment support for fixed bridgework. It is intended for delayed loading.<br><br>TS Fixture System is compatible with abutment in the ET/SS Implant System. | Similar |
| Surgery type | One or two stage Surgery | One or two stage Surgery | Similar |
| Structure | - Internal Hex-Connected<br>- Submerged Fixture<br>- Tapered body shape<br>- 3 sided cutting edge with self-tapping | - Internal Hex-Connected<br>- Submerged Fixture<br>- Tapered body shape and straight body shape<br>- 4 sided cutting edge with self-tapping | Different |
| Body Diameter (D) | 3.75, 4.2, 4.6, 5.05 | TSIII SA Fixture: 3.75, 3.77, 4.2, 4.25, 4.6, 4.63, 4.65, 5.05, 5.08, 5.1, 5.92, 5.95, 6, 6.8 | Different |
| Implant Length (mm) | 3.75mm diameter:<br>Length: 8.5, 10, 11.5, 13, 15;<br>4.2mm diameter:<br>Length: 7, 8.5, 10, 11.5, 13, 15;<br>4.6mm diameter:<br>Length: 7, 8.5, 10, 11.5, 13, 15;<br>5.05mm diameter:<br>Length: 7, 8.5, 10, 11.5, 13, 15; | For 3.75 to 5.1mm implant<br>Length: 7.0~15.0<br>For 5.92 to 6.8mm implant<br>Length: 7.0~12.5 | Different |
| Material of Fixture | Pure Titanium Grade 4 (ASTM F67) | Pure Titanium Grade 4 (ASTM F67) | Similar |
| Surface | SA | SA | Similar |
| Sterilization | Radiation Sterile | Radiation Sterile | Similar |
| Shelf life | 5 years | 8 years | Different |

Different - Structure

The structure of the proposed device is different from the predicated device. The proposed device is 3 sided cutting edge with self-tapping, while the predicate device is a 4 sided cutting edge with self-tapping. However, mechanical test has been conducted on the proposed device and predicate device and the test result does not show any significant difference in regard of mechanical strength. Therefore, this difference will not affect substantially equivalence.

Different - Body Diameter

The body diameter of the proposed device is not same as the predicate device. However, the proposed diameter range can be covered by the predicated device. Therefore, this difference will not affect substantially equivalence.

Different - Implant Length

The implant length for each diameter size of the proposed device is not same as the predicate device. However, the proposed implant length for each diameter size can be covered by the predicated device. Therefore, this difference will not affect substantially equivalence.

Different - Shelf life

The shelf life of the proposed device is different from the predicate device. The shelf life is based on an assessment of the seal integrity of the sterile barrier packaging and mechanical strength test of the aged samples. The assessment showed that the proposed device can maintain its performance and package integrity during the period of shelf life. Therefore, this difference will not affect substantially equivalence.

Table 2 Characteristic Comparison of Abutment

<table>
<tr><td colspan="4">Healing Abutment</td></tr>
<tr><td>ITEM</td><td>Proposed Device</td><td>Reference Device K192436</td><td>Remark</td></tr>
<tr><td>Dimension (mm)</td><td><table><tr><td>D(Ø)</td><td>Length</td></tr><tr><td>4.8</td><td>7.5,8.5,9.5,10.5,11.5</td></tr><tr><td>5.3</td><td>8.5,9.5,10.5,11.5,12.5</td></tr><tr><td>6.3</td><td>8.5,9.5,10.5,11.5,12.5</td></tr><tr><td>7.3</td><td>8.5,9.5,10.5,11.5,12.5</td></tr></table></td><td>Diameter: 4.04 / 4.12 / 4.14 / 4.20 / 4.50 / 4.54 / 4.64 / 4.70 / 4.80/5.50 / 5.45 / 5.64 / 5.75 /6.50 / 6.54 / 6.64 / 6.74 / 7.54 / 7.64 / 8.54 / 8.64 / 9.54 / 9.64<br>Length: 6.15/6.30/7.15/7.30/8.15/8.30/8.88 / 8.89 / 8.90 / 9.15/9.30/10.81 / 10.83 / 10.96 / 11.05 / 11.06 / 11.09 / 12.31 / 12.34 /12.45 / 12.55 / 12.56 / 12.57 / 14.32 / 14.34 / 14.51 / 14.56</td><td>Different</td></tr>
<tr><td>Materials</td><td>Titanium Alloy (Ti-6Al-4V, ASTM F136)</td><td>Titanium Alloy (Ti-6Al-4V, ASTM F136)</td><td>Similar</td></tr>
<tr><td>Principle of operation</td><td>Healing abutments are screwed into the implant to protect the inner configuration</td><td>Healing abutments are screwed into the implant to protect the inner configuration</td><td>Similar</td></tr>
<tr><td colspan="4">Straight Abutment</td></tr>
<tr><td>ITEM</td><td>Proposed Device</td><td>Reference Device K161689</td><td>Remark</td></tr>
<tr><td>Materials</td><td>Titanium Alloy (Ti-6Al-4V, ASTM F136)</td><td>Titanium Alloy (Ti-6Al-4V, ASTM F136)</td><td>Similar</td></tr>
<tr><td>Principle of operation</td><td>Use for marking general cement-type prosthesis</td><td>Use for marking general cement-type prosthesis</td><td>Similar</td></tr>
<tr><td>Dimension (mm)</td><td><table><tr><td>D(Ø)</td><td>G/H</td><td>H</td></tr><tr><td>4.6</td><td>1, 2, 3, 4, 5</td><td>5.5</td></tr><tr><td>5</td><td>1, 2, 3, 4, 5</td><td>4.0, 5.5, 7.0</td></tr><tr><td>6</td><td>1, 2, 3, 4, 5</td><td>4.0, 5.5, 7.0</td></tr><tr><td>7</td><td>1, 2, 3, 4, 5</td><td>5.5</td></tr></table></td><td><table><tr><td>D(Ø)</td><td>G/H</td><td>H</td></tr><tr><td>4.6</td><td>1, 2, 3, 4, 5</td><td>5.5, 7</td></tr><tr><td>5</td><td>1, 2, 3, 4, 5</td><td>4.0, 5.5, 7.0</td></tr><tr><td>6</td><td>1, 2, 3, 4, 5</td><td>4.0, 5.5, 7.0</td></tr><tr><td>7</td><td>1, 2, 3, 4, 5</td><td>5.5</td></tr></table></td><td>Different</td></tr>
<tr><td colspan="4">Angle Abutment</td></tr>
<tr><td>ITEM</td><td>Proposed Device</td><td>Reference Device K182091</td><td>Remark</td></tr>
<tr><td>Materials</td><td>Titanium Alloy (Ti-6Al-4V,</td><td>Titanium Alloy (Ti-6Al-4V, ASTM</td><td>Similar</td></tr>
</table>

<table>
<tr><td></td><td>ASTM F136)</td><td>F136)</td><td></td></tr>
<tr><td>Principle of operation</td><td>Using making general cement type prosthesis when a prosthetic’s path adjustment is necessary.</td><td>Using making general cement type prosthesis when a prosthetic’s path adjustment is necessary.</td><td>Similar</td></tr>
<tr><td>Angle</td><td>17°</td><td>17°</td><td>Similar</td></tr>
<tr><td>Diameter (mm)</td><td>4.5, 5, 6</td><td>4, 4.5, 5, 6</td><td>Different</td></tr>
<tr><td>Height (mm)</td><td>8</td><td>8</td><td>Similar</td></tr>
<tr><td>Design feature</td><td>A type, B type, Non-Hex</td><td>A type, B type, Non-Hex</td><td>Similar</td></tr>
<tr><td colspan="4">Multi Abutment</td></tr>
<tr><td>ITEM</td><td>Proposed Device</td><td>Reference Device K152509</td><td>Remark</td></tr>
<tr><td>Materials</td><td>Titanium Alloy (Ti-6Al-4V, ASTM F136)</td><td>Titanium Alloy (Ti-6Al-4V, ASTM F136)</td><td>Similar</td></tr>
<tr><td>Principle of operation</td><td>Use for fabricating screw retained prosthesis</td><td>The Multi-unit Abutment is used for fabricating screw retained prosthesis</td><td>Similar</td></tr>
<tr><td>Dimension (mm)</td><td><table><tr><td>D(Ø)</td><td>G/H</td></tr><tr><td>4</td><td>1, 2, 3, 4</td></tr><tr><td>4.8</td><td>1, 2, 3, 4</td></tr><tr><td>5</td><td>1, 2, 3, 4</td></tr><tr><td>5.5</td><td>1, 2, 3, 4,</td></tr><tr><td>6</td><td>1, 2, 3, 4</td></tr></table></td><td><table><tr><td>D(Ø)</td><td>G/H</td></tr><tr><td>3.3</td><td>0.5, 2.0, 4</td></tr><tr><td>3.8</td><td>0.5, 2.0, 4</td></tr><tr><td>4.3</td><td>0.5, 2.0, 4</td></tr><tr><td>5.0</td><td>0.5, 2.0, 4</td></tr><tr><td>6.0</td><td>0.5, 2.0, 4</td></tr></table></td><td>Different</td></tr>
<tr><td colspan="4">Multi-Angled Abutment</td></tr>
<tr><td>ITEM</td><td>Proposed Device</td><td>Reference Device K152509</td><td>Remark</td></tr>
<tr><td>Materials</td><td>Titanium Alloy (Ti-6Al-4V, ASTM F136)</td><td>Titanium Alloy (Ti-6Al-4V, ASTM F136)</td><td>Similar</td></tr>
<tr><td>Principle of operation</td><td>Multi Angled Abutment is used fabricating screw retained prosthesis and correcting the prosthetic angulation of implant.</td><td>The Multi-unit Angled Abutment is used for fabricating screw retained prosthesis and correcting the prosthetic angulation of implant.</td><td>Similar</td></tr>
<tr><td>Angle</td><td>17°, 30°</td><td>17°, 30°</td><td>Similar</td></tr>
<tr><td>Diameter (mm)</td><td>4.8</td><td>3.3, 3.8, 4.3, 5.0</td><td>Different</td></tr>
<tr><td>GH (mm)</td><td>2.5, 3, 3.5, 4, 5</td><td>2.5, 3.5, 4.0, 5.0</td><td>Different</td></tr>
<tr><td>Design feature</td><td>Hex</td><td>Hex</td><td>Similar</td></tr>
<tr><td colspan="4">Temporary Abutment</td></tr>
<tr><td>ITEM</td><td>Proposed Device</td><td>Reference Device K161689</td><td>Remark</td></tr>
</table>

<table>
<tr><td>Materials</td><td>Titanium Alloy (Ti-6Al-4V, ASTM F136)</td><td>Titanium Alloy (Ti-6Al-4V, ASTM F136)</td><td>Similar</td></tr>
<tr><td>Principle of operation</td><td>Cement/screw retained restoration; using making temporary prosthesis to maintain aesthetic appearance until final prosthesis is made.</td><td>Cement/screw retained restoration; using making temporary prosthesis to maintain aesthetic appearance until final prosthesis is made.</td><td>Similar</td></tr>
<tr><td>Dimension (mm)</td><td><table><tr><td>D(Ø)</td><td>G/H</td></tr><tr><td>4</td><td>1, 3</td></tr><tr><td>4.5</td><td>1, 3</td></tr></table></td><td><table><tr><td>D(Ø)</td><td>G/H</td></tr><tr><td>4</td><td>1, 3</td></tr><tr><td>4.5</td><td>1, 3</td></tr></table></td><td>Similar</td></tr>
<tr><td>Design feature</td><td>Hex, Non-Hex</td><td>Hex, Non-Hex</td><td>Similar</td></tr>
<tr><td colspan="4">Straight Cylinder</td></tr>
<tr><td>ITEM</td><td>Proposed Device</td><td>Reference Device K120847</td><td>Remark</td></tr>
<tr><td>Materials</td><td>Titanium Alloy (Ti-6Al-4V, ASTM F136)</td><td>Titanium Gr. 3 (ASTM F67)</td><td>Different</td></tr>
<tr><td>Principle of operation</td><td>Using making combination retained type prosthesis with using Multi Abutment or Mutli-Angled Abutment together by creating framework of the final prosthesis to be fixed on top of the abutment.</td><td>Using making combination retained type prosthesis with using Multi Abutment together by creating framework of the final prosthesis to be fixed on top of the abutment.</td><td>Similar</td></tr>
<tr><td>Diameter (mm)</td><td>4, 5, 6, 4.8, 5.5</td><td>4.2~6.3</td><td>Different</td></tr>
<tr><td>Length (mm)</td><td>7.0</td><td>7</td><td>Similar</td></tr>
<tr><td colspan="4">Angled Cylinder</td></tr>
<tr><td>ITEM</td><td>Proposed Device</td><td>Reference Device K182091</td><td>Remark</td></tr>
<tr><td>Materials</td><td>Titanium Alloy (Ti-6Al-4V, ASTM F136)</td><td>Titanium Gr. 3 (ASTM F67)</td><td>Different</td></tr>
<tr><td>Principle of operation</td><td>Using making combination retained type prosthesis by using with Multi Abutment together when path adjustment is necessary.</td><td>Using making combination retained type prosthesis by using with Convertible Abutment together when path adjustment is necessary.</td><td>Similar</td></tr>
<tr><td>Diameter (mm)</td><td>4, 5, 6</td><td>4.2, 5.0, 6.3</td><td rowspan="2">Different</td></tr>
<tr><td>Length (mm)</td><td>8</td><td>7.8</td></tr>
<tr><td>Angle (°)</td><td>17</td><td>17</td><td>Similar</td></tr>
<tr><td>Design feature</td><td>Hex</td><td>Hex, Non-Hex, Octa.</td><td>Different</td></tr>
</table>

<table>
<tr><td colspan="4">Temporary Cylinder</td></tr>
<tr><td>ITEM</td><td>Proposed Device</td><td>Reference Device K182091</td><td>Remark</td></tr>
<tr><td>Materials</td><td>Titanium Alloy (Ti-6Al-4V, ASTM F136)</td><td>Titanium Gr. 3 (ASTM F67)</td><td>Different</td></tr>
<tr><td>Principle of operation</td><td>Screw retained restoration; using making temporary prosthesis before loading final prosthesis by connected with Multi Abutment, or Mutli- Angled Abutment to make overdenture and bridge as multiple cases</td><td>Screw retained restoration; using making temporary prosthesis before loading final prosthesis by connected with Multi Abutment, US Multi Angled Abutment or Esthetic-low Abutment to make overdenture and bridge as multiple cases</td><td>Similar</td></tr>
<tr><td>Diameter (mm)</td><td>4.8, 5.5</td><td>4.8, 5.5</td><td>Similar</td></tr>
<tr><td>Height (mm)</td><td>12</td><td>12</td><td>Similar</td></tr>
<tr><td>Design feature</td><td>Non-Hex</td><td>Hex, Non-Hex</td><td>Different</td></tr>
<tr><td colspan="4">Abutment Screw</td></tr>
<tr><td>ITEM</td><td>Proposed Device</td><td>Reference Device K161689</td><td>Remark</td></tr>
<tr><td>Materials</td><td>Titanium Alloy (Ti-6Al-4V, ASTM F136)</td><td>Titanium Alloy (Ti-6Al-4V, ASTM F136)</td><td>Similar</td></tr>
<tr><td>Principle of operation</td><td>Abutment screw is used to connect an abutment to the fixture</td><td>Abutment screw is used to connect an abutment to the fixture</td><td>Similar</td></tr>
<tr><td>Dimension (mm)</td><td><table><tr><td>D(Ø)</td><td>Post height</td></tr><tr><td>2</td><td>7.5, 9.6</td></tr><tr><td>2.2</td><td>10.2</td></tr><tr><td>2.32</td><td>8.36</td></tr></table></td><td><table><tr><td>D(Ø)</td><td>Post height</td></tr><tr><td>2</td><td>7.5, 9.6</td></tr><tr><td>2.2</td><td>10.2</td></tr><tr><td>2.3</td><td>8.35</td></tr></table></td><td>Similar</td></tr>
<tr><td colspan="4">Cylinder Screw</td></tr>
<tr><td>ITEM</td><td>Proposed Device</td><td>Reference Device K182091</td><td>Remark</td></tr>
<tr><td>Materials</td><td>Titanium Alloy (Ti-6Al-4V, ASTM F136)</td><td>Titanium Alloy (Ti-6Al-4V, ASTM F136)</td><td>Similar</td></tr>
<tr><td>Principle of operation</td><td>Cylinder screw is used to connect a cylinder to the abutment.</td><td>Cylinder screw is used to connect a cylinder to the abutment.</td><td>Similar</td></tr>
<tr><td>Dimension (mm)</td><td><table><tr><td>D(Ø)</td><td>G/H</td></tr><tr><td>2.2</td><td>4.3</td></tr><tr><td>2.4</td><td>4.3</td></tr></table></td><td><table><tr><td>D(Ø)</td><td>G/H</td></tr><tr><td>2.2</td><td>4.35</td></tr><tr><td>2.5</td><td>4.9</td></tr></table></td><td>Different</td></tr>
</table>

| | | | | |
|---|---|---|---|---|
| | 2.5 | 4.3 | | |

Different - Dimension of Healing Abutment
The diameter and height of the proposed healing abutment is not same as the reference device, however, the proposed diameter and length range can be covered by the reference device K192436. Therefore, this difference does not affect substantially equivalence.

Similar – Diameter of Straight Abutment
The diameter of the proposed straight abutment is the same as the reference device, while the height of the proposed 4.6mm straight abutment is not same as the reference device. However, the proposed height range can be covered by the reference device K161689. Therefore, this difference does not affect substantially equivalence.

Similar - Diameter of Angle Abutment
The diameter of the proposed angle abutment is less than the reference device, however, the diameter range can be covered by the reference device K182091. Therefore, this difference does not affect substantially equivalence.

Similar - Dimension of Multi Abutment
The diameter of the proposed multi abutment is not same as the reference device. However, the proposed diameter range and gingiva height range can be covered by the reference device K152509. Therefore, this difference does not affect substantially equivalence.

Different - Diameter of Multi-Angled Abutment
The diameter of the proposed multi-angled abutment is not same as the reference device. However, the proposed diameter can be covered by the reference device K152509. Therefore, this difference does not affect substantially equivalence.

Similar - Gingiva Height of Multi-Angled Abutment
The gingiva height of the proposed multi-angled abutment is not same as the reference device. However, the proposed gingiva height range can be covered by the reference device K152509. Therefore, this difference does not affect substantially equivalence.

Different - Materials of Straight Cylinder
The material of the proposed straight cylinder is different from the reference device K120847. However, the biocompatibility evaluation was performed on the proposed device and the result demonstrate that this material does not cause any adverse effects. Therefore, this difference does not affect substantially equivalence.

Similar – Diameter of Straight Cylinder

The diameter of the proposed straight cylinder is not same as the reference device, however, diameter of the proposed straight cylinder can be covered by the reference device K120847. Therefore, this difference does not affect substantially equivalence.

Different - Materials of Angled Cylinder
The material of the proposed angled cylinder is different from the reference device K182091. However, the biocompatibility evaluation was performed on the proposed device and the result demonstrate that this material does not cause any adverse effects. Therefore, this difference does not affect substantially equivalence.

Similar - Diameter and Length of Angled Cylinder
Although the diameter and length of the proposed angled cylinder is different from the reference device K182091. The proposed diameter range can be covered by the reference device and the proposed length is very approach to the reference device. The difference is very slight. In addition, mechanical test has been conducted on the proposed device and the test result does not show any significant difference in regard of mechanical strength. Therefore, this difference does not affect substantially equivalence.

Similar - Design feature of Angled Cylinder
The design of angled cylinder is hexagonal design, which can be covered by the design of reference device K182091 including hexagonal, non-hexagonal and octagonal design. Therefore, this difference does not affect substantially equivalence.

Different - Materials of Temporary Cylinder
The material of the proposed temporary cylinder is different from the reference device K182091. However, the biocompatibility evaluation was performed on the proposed device and the result demonstrate that this material does not cause any adverse effects. Therefore, this difference does not affect substantially equivalence.

Different - Design feature of Temporary Cylinder
The design of temporary cylinder is non-hexagonal design, which can be covered by the design of reference device K182091 including hexagonal and non-hexagonal design. Therefore, this difference does not affect substantially equivalence.

Similar – Dimension of Cylinder Screw
The diameter of the proposed cylinder screw is not same as the reference device, the proposed device is available in an additional size, 2.4mm. However, the proposed diameter range can be covered by the reference device K182091. And the proposed device provides more options for clinical situations.
The gingiva height of the proposed cylinder screw is different from the reference device K182091. The gingiva height of the proposed cylinder screw only has a size of 4.3mm, which is slightly different from the 4.35mm of the reference device K182091. In addition, mechanical test has been conducted on the

proposed device and the test result does not show any significant difference in regard of mechanical strength. Therefore, this difference does not affect substantially equivalence.

10. Conclusion

The conclusions drawn from the non-clinical tests demonstrate that the subject device is substantially equivalent to legally marketed reference device and predicate device