ARUM DENTISTRY Co., Ltd.
Won-Yi Choi
Official Correspondent
23, Gukjegwahak 11-ro, Yuseong-gu
Daejeon, 34002
REPUBLIC OF KOREA

June 5, 2024

Re: K240603
Trade/Device Name: Ti-Base & Master Fix
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: March 4, 2024
Received: March 4, 2024

Dear Won-Yi Choi:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

Andrew I. Steen
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
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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)*
K240603

Device Name

Ti-Base & Master Fix

Indications for Use *(Describe)*

The Ti-Base & Master Fix are intended to be used in conjunction with endosseous dental implants in the maxillary or mandibular arch to provide support for prosthetic restorations. All digitally-designed Ti-Base and Master Fix are intended to be sent to an ARUM DENTISTRY validated milling center for manufacture.

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.

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## 7. 510(K) Summary

### Submitter

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### Device Information

- Trade Name: Ti-Base & Master Fix
- Common Name: Endosseous Dental Implant Abutment
- Classification Name: Abutment, Implant, Dental, Endosseous
- Product Code: NHA
- Panel: Dental
- Regulation Number: 21 CFR 872.3630
- Device Class: Class II
- Date Prepared: 06/04/2024

### Predicate Devices

The subject device is substantially equivalent to the following predicate devices:

Primary Predicate

- K191986, DESS Dental Smart Solutions by Terrats Medical SL

Reference Device

- K190112, Non-Sterile Zirconia Block (Model: Finebase, Montblanc, Trione HT, Trione C, Trione HT+) by Fine Advanced Compound Co., Ltd
- K193260, U-Cem Premium & MAZIC Cem by Vericom Co., Ltd.
- K213506, NB 1 SA Implant System by ARUM DENTISTRY Co., Ltd.
- K230725, NB Implant System by ARUM DENTISTRY Co., Ltd.

**General Description**

Device Components

1) Abutment
   - Ti-Base
   - Master Fix
   - Abutment Screw

The Ti-Base and Master Fix consist of a two-piece abutment, where the titanium base is pre-manufactured abutment that will be used to support a CAD/CAM designed superstructure (the second part of the two-piece abutment) that compose the final abutment.

The dimension ranges of the subject device are below:

| No. | Device Name | Dimension |
|---|---|---|
| 1 | Ti-Base | Ø3.35 (D) x 4.0 mm (Post Height) |
| 2 | Master Fix | Ø4.5, 5.5, 6.5 (D) x 3.5, 4.0, 5.0, mm (Post Height) |
| 3 | Abutment Screw (Cleared in K213506) | Ø 2.35 (D) x 8.4 mm(L) |
| 4 | Master Fix Screw | Ø2.25 (D) x 10.3, 11.3, 11.8, 12.3, 12.8, 13.3, 13.8, 14.3, 14.8, 15.3, 15.8mm (L) |

Below are the abutment's features:

| Name | Uses | Surface |
|---|---|---|
| Ti-Base | The Ti-Base is used as a support of prosthesis to restore the patient's chewing function. | N/A |
| Master Fix | The Master Fix is used as a support of prosthesis to restore the patient's chewing function. | N/A |
| Abutment Screw (Cleared in K213506) | The Abutment Screw is used for connect fixture and abutment. | N/A |
| Master Fix Screw | The Abutment Screw is used for connect fixture and abutment. | N/A |

Ti-Base, Master Fix, Abutment Screw and Master Fix Screw are provided non-sterilized.

Ti-Base is enclosed with Abutment Screw in a packing. Master Fix is enclosed with Master Fix Screw in a packing. These devices are intended for single use only. All digitally designed custom abutments for use with Ti-Base or Master Fix are to be sent to ARUM DENTISTRY validated milling center for manufacture. All superstructures are to be manufactured from zirconia (cleared

K190112). Digitally designed CAD/CAM abutments must have a 0.5 mm minimum gingival height dimension.

The Titanium Base abutment is composed of two-piece abutment that is a titanium base at the bottom and a zirconia superstructure (CAD/CAM patient specific superstructure) at the top. The zirconia superstructure is straight only and is not to be designed to provide an angle or divergence correction.

For the Ti-Base the design parameters for the CAD/CAM zirconia superstructure are:

Minimum wall thickness – 0.5 mm;

Minimum post height* for single-unit restorations – 4.5 mm;

Maximum gingival height – 5.0 mm;

Minimum gingival height – 0.5 mm;

Angulation - 0°

and All zirconia superstructures are for straight abutments only.

*Post Height is measured above the gingival height of the final patient-matched design

For the Master Fix, the design parameters for the CAD/CAM zirconia superstructure are:

Minimum wall thickness – 0.5 mm;

Minimum post height* for single-unit restorations – 4.0 mm;

Maximum gingival height – 5.0 mm;

Minimum gingival height – 0.5 mm;

Angulation - 0°

and All zirconia superstructures are for straight abutments only.

*Post Height is measured above the gingival height of the final patient-matched design

The Ti-Base and Master Fix is compatible with the following implant systems.

| Manufacturer | 510(k) No. | Implant System Compatibility | Dimension |
|---|---|---|---|
| ARUM DENTISTRY Co., Ltd. | K213506 | NB 1 SA Implant System | Ø 3.8, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5 |
| | K230725 | NB Implant System | Ø 3.8, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5 |

The titanium bases are used as part of a two-piece abutment, where the base is premanufactured from titanium alloy (Ti-6Al-4V Eli) and the top half is a CAD/CAM zirconia superstructure, milled at a validated milling center. These pieces are cemented together to form the final abutment.

Raw material Zirconia Block

K190112, Non-Sterile Zirconia Block by FINE ADVANCED COMPOUND Co., Ltd.

Dental Cement

K193260, U-Cem Premium & MAZIC Cem by Vericom Co., Ltd.

Zirconia structure Details

| Specification | Zirconia Block |
|---|---|
| Trade name | Non-Sterile Zirconia Block |
| Common name | Dental zirconia blanks/blocks |
| Manufacturer | FINE ADVANCED COMPOUND Co., Ltd |
| 510(k) No. | K190112 |
| Product code | EIH |
| Regulatory class | Class II |
| Intended use | Non-Sterile Zirconia Block (Model name: Finebase, Montblanc, Trione HT, Trione C, Trione HT+) are indicated for the production of artificial teeth in fixed or removable dentures, or for jacket crowns, facings, and veneers. |

**Indication for Use**

Ti-Base & Master Fix are intended to be used in conjunction with endosseous dental implants in the maxillary or mandibular arch to provide support for prosthetic restorations.

All digitally-designed Ti-Base and Master Fix are intended to be sent to an ARUM DENTISTRY validated milling center for manufacture.

**Materials**

Pre-Manufactured titanium components of Abutments and Abutment Screws are fabricated from Ti-6Al-4V Eli (Conforming to ASTM F136).

**Summaries of Technology Characteristics**

1) Ti-Base

| | Subject Device | Primary Predicate |
|---|---|---|
| Manufacturer | ARUM DENTISTRY Co., Ltd. | Terrats Medical SL |
| Device Name | Ti-Base & Master Fix | DESS Dental Smart Solutions |
| 510(k) No. | N/A | K191986 |
| Intended Use/ Indications for use | Ti-Base & Master Fix are intended to be used in conjunction with endosseous dental implants in the maxillary or mandibular arch to provide support for prosthetic restorations.<br>All digitally-designed Ti-Base and Master Fix are intended to be sent to an ARUM DENTISTRY validated milling center for manufacture. | DESS Dental Smart Solutions abutments are intended to be used in conjunction with endosseous dental implants in the maxillary or mandibular arch to provide support for prosthetic restorations.<br>All digitally designed custom abutments for use with Ti Base abutments or Pre-milled (Blank) abutments are to be sent to a Terrats Medical validated milling center for manufacture. |
| Diameter (ø) | 3.35 | 4.5 – 6.5 |
| Material | Ti-6Al-4V Eli | Ti-6Al-4V Eli |
| Superstructure Material | Zirconia (Y-TZP)<br>Non-Sterile Zirconia Block, cleared in K190112 | Zirconia (Y-TZP)<br>(Not stated in 510(k) Summary) |
| Cement Material | Cement<br>U-Cem Premium & MAZIC Cem, cleared in K193260 | Multilink Hybrid Abutment Cement<br>(Ivoclar Vivadent AG, Cleared in K130436) |
| Sterilization | End User Sterilization | End User Sterilization |
| Design Parameter | Minimum wall thickness – 0.5 mm;<br>Minimum post height for single-unit restorations – 4.5 mm;<br>Maximum gingival height – 5.0 mm<br>Minimum gingival height – 0.5 mm<br>Angulation - 0° | Minimum wall thickness – 0.4 mm<br>Minimum post height – 4.2 mm<br>Maximum gingival height – 6.0 mm |

| | |
|---|---|
| Substantial Equivalent Discussion | **1. Similarities**<br>The Ti-Base has the same intended use for, technological characteristics to the K191986. The Ti-Base have same device characteristics with the Primary Predicate such as material, sterilization, intended use, functions, structure.<br><br>**2. Differences**<br>The minor differences with the primary predicated K191986 are slightly different dimension and insignificant shapes. However, the subject diameters are in the range of diameters of primary predicate and this dimensional difference doesn't affect device safety and effectiveness. The shape is only for the manufacture's properties such as design and compatible to their own dental implant design. These minor differences do not impact safety and effectiveness because these differences are related to the compatible implant design and are mitigated by the mechanical performing testing. |

2) Master Fix

| | Subject Device | Primary Predicate |
|---|---|---|
| Manufacturer | ARUM DENTISTRY Co., Ltd. | Terrats Medical SL |
| Device Name | Ti-Base & Master Fix | DESS Dental Smart Solutions |
| 510(k) No. | N/A | K191986 |
| Intended Use/ Indications for use | Ti-Base & Master Fix are intended to be used in conjunction with endosseous dental implants in the maxillary or mandibular arch to provide support for prosthetic restorations.<br>All digitally designed abutments for use with Ti-Base and Master Fix are intended to be manufactured at an ARUM DENTISTRY validated milling center. | DESS Dental Smart Solutions abutments are intended to be used in conjunction with endosseous dental implants in the maxillary or mandibular arch to provide support for prosthetic restorations.<br>All digitally designed custom abutments for use with Ti Base abutments or Pre-milled (Blank) abutments are to be sent to a Terrats Medical validated milling center for manufacture. |
| Diameter (ø) | 4.5, 5.5, 6.5 | 4.5 – 6.5 |
| Material | Ti-6Al-4V Eli | Ti-6Al-4V Eli |
| Superstructure Material | Zirconia (Y-TZP)<br>Non-Sterile Zirconia Block, cleared in K190112 | Zirconia (Y-TZP)<br>(Not stated in 510(k) Summary) |
| Cement Material | Cement<br>U-Cem Premium & MAZIC Cem, cleared in K193260 | Multilink Hybrid Abutment Cement<br>(Ivoclar Vivadent AG, Cleared in K130436) |
| Sterilization | End User Sterilization | End User Sterilization |
| Design Parameter | Minimum wall thickness – 0.5 mm;<br>Minimum post height for single-unit restorations – 4.5 mm;<br>Maximum gingival height – 5.0 mm<br>Minimum gingival height – 0.5 mm<br>Angulation - 0° | Minimum wall thickness – 0.4 mm<br>Minimum post height – 4.2 mm<br>Maximum gingival height – 6.0 mm |

| | |
|---|---|
| Substantial Equivalent Discussion | **1. Similarities**<br>The Master Fix has the same intended use for, technological characteristics to the K191986. The Master Fix have same device characteristics with the Primary Predicate such as material, sterilization, intended use, functions, structure.<br><br>**2. Differences**<br>The predicate device has a notch for anti-rotation, but the subject device features an enhanced anti-rotation design with two flat surfaces to prevent rotation between the zirconia superstructure and the abutment, allowing for precise positioning and orientation of the superstructure.<br>The subject device features a slot in the post design, providing a larger area for improved cement adhesion, with differences in shape and design compared to the predicate device. These differences have been validated through mechanical performance testing and do not affect safety or effectiveness. Therefore, the design changes aim to improve the stability and retention of the prosthesis. |

3) Abutment Screw

| | Subject Device | Reference Device |
|---|---|---|
| Manufacturer | ARUM DENTISTRY Co., Ltd. | ARUM DENTISTRY Co., Ltd. |
| Device Name | Ti-Base & Master Fix | NB 1 SA Implant System |
| 510(k) No. | N/A | K213506 |
| Material | Ti-6Al-4V Eli | Ti-6Al-4V Eli |
| Range of Diameters (Ø) | 2.2 | 2.35 |
| Length (mm) | 10.8 | 8.4 |
| Sterilization | End User Sterilization | End User Sterilization |
| Substantial Equivalent Discussion | **1. Similarities**<br>The Abutment Screw has same indication for use, principle of operation, functions, and material to the predicate K213506.<br><br>**2. Differences**<br>The difference between the subject and reference device is the dimensions of the device. However, it does not affect device's fundamental functions and safety; therefore, it is substantial equivalent. | |

4) Master Fix Screw

| | Subject Device | Reference Device |
|---|---|---|
| Manufacturer | ARUM DENTISTRY Co., Ltd. | ARUM DENTISTRY Co., Ltd. |
| Device Name | Ti-Base & Master Fix | NB 1 SA Implant System |
| 510(k) No. | N/A | K213506 |
| Material | Ti-6Al-4V Eli | Ti-6Al-4V Eli |
| Range of Diameters (Ø) | 2.25 | 2.35 |
| Length (mm) | 10.3, 11.3, 11.8, 12.3, 12.8, 13.3, 13.8, 14.3, 14.8, 15.3, 15.8 | 8.4 |
| Sterilization | End User Sterilization | End User Sterilization |
| Substantial Equivalent Discussion | **1. Similarities**<br>The Abutment Screw has same indication for use, principle of operation, functions, to secure a dental abutment to a dental implant in the upper or lower jaw, and material to the predicate K213506.<br><br>**2. Differences**<br>The screw's design features a larger head to increase retention in screw-retained prostheses. The extended head fills the abutment's empty space, enhancing stability and preventing screw fractures. Additionally, the design facilitates easier access for the screw driver.<br>However, it does not affect device's fundamental functions and safety; therefore, it is substantial equivalent. | |

**Performance Data**

Non-clinical data submitted to demonstrate substantial equivalence include: biocompatibility testing according to ISO 10993-5 and ISO 10993-12 and moist heat sterilization validation according to ISO 17665 -1 and ISO 17665-2.

No clinical data were included in this submission.

**MR Environment Condition**

Non-Clinical worst-case MRI review was performed to evaluated the NB Mini Implant System devices in the MRI environment using scientific rationale and published literature (e.g., Terry O. Woods, Jana Delfino, & Sunder Rajan. (2019). Assessment of Magnetically Induced Displacement Force and Torque on Metal Alloys Used in Medical Devices. *Journal of Testing and Evaluation* 49.2, 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.

**Conclusion**

The Subject device and the Primary predicate device have the same intended use, have the same technological characteristics, and are made of the same materials. The Subject device and the Primary predicate device encompass the same range of physical dimensions and are to be sterilized using the same methods. Although there is slightly difference design of the anti-rotation feature, this difference is the same purpose. This minor difference do not impact safety and effectiveness because this difference are related to increase the adhesion of cement to the prosthesis. The data included in this premarket notification demonstrate substantial equivalence to the primary predicate device listed above. Therefore, the subject device and primary predicate device are substantial equivalence.