September 25, 2020

Medimecca Co., Ltd.
% Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Inc.
1150 Roosevelt STE 200
Irvine, California 92620

Re: K202039
Trade/Device Name: Honorst Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: August 22, 2020
Received: August 27, 2020

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. 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.
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: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*

Device Name

Honorst Implant System

Indications for Use *(Describe)*

Honorst Implant System is intended for use in partially or fully edentulous mandibles and maxilla, in support of single of multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. Honorst Implant System is for single stage and two stage surgical procedures. This system 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.**

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**510(k) Summary**
**(**K202039)

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

Date: 09/25/2020

## 1. Submitter/Applicant

Medimecca Co., Ltd.
Daeryung Techno Town 3-Cha 104, 105, 109, 110 Gasan-Dong,
115, Gasan Digital 2-Ro, Geumcheon-Gu
Seoul, Republic of Korea, 08505

## 2. U.S Agent/Contact Person

Priscilla Chung
LK Consulting Group USA, Inc.
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## 3. Device

- Trade Name: Honorst Implant System
- Common Name: Dental Implant System
- Classification: Class II
- Classification regulation: 21 CFR 872.3640
- Product Code: DZE, NHA

## 4. Predicate Devices:

Primary Predicate Device:
CHAORUM Implant System (K160536) by MEDIMECCA Co., Ltd.

Reference Devices:
- 3I OSSEOTITE CERTAIN DENTAL IMPLANTS (K063341) by IMPLANT INNOVATIONS, INC.
- TS Fixture System (K121995) by OSSTEM Implant Co., Ltd.

## 5. Description:

Honorst Implant System are devices made of titanium intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices such as artificial teeth, and to restore the patients chewing function.
Honorst Implant System consists of fixtures, abutments, and screws. Its material, structure and intended use are substantial equivalent to the predicate devices in the market. Honorst Implant System offers two different implants in SLA treatment and also offers two different onebody implants in SLA treatment.
The Milling Abutment is only to be hand milled and not undergo CAD/CAM fabrication.

### 5.1. Fixtures – SLA (Titanium Gr4, ASTM F67)

| **Size** |
|---|
| NP (Narrow Platform) Connection Type Fixture<br>3.75mm Dia. x 8.5mm (L) / 10.0mm (L) / 11.5mm (L) / 13.0mm (L)<br><br>RP (Regular Platform) Connection Type Fixture<br>4.20mm Dia. x 7.0mm (L) / 8.5mm (L) /10.0mm (L) / 11.5mm (L) / 13.0mm (L)<br>4.60mm Dia. x 7.0mm (L) / 8.5mm (L) / 10.0mm (L) / 11.5mm (L) / 13.0mm (L)<br>5.10mm Dia. x 7.0mm (L) / 8.5mm (L) / 10.0mm (L) / 11.5mm (L) / 13.0mm (L)<br>5.50mm Dia. x 7.0mm (L) / 8.5mm (L) / 10.0mm (L) / 11.5mm (L) / 13.0mm (L)<br>6.00mm Dia. x 7.0mm (L) / 8.0mm (L) / 9.5mm (L) / 11.0mm (L) / 12.5mm (L) |

### 5.2. Abutments

- NP (Narrow Platform) Connection Type Abutments

| Abutments | Material | Dia. (mm) | Gingival Height |
|---|---|---|---|
| Dual Abutment | Titanium Gr4, ASTM F67 | 4.0 / 4.6 | 1.0 / 2.0 / 3.0 / 4.0 / 5.0 |
| Combi Abutment | | 4.0 / 4.6 / 4.8 | 1.0 / 2.0 / 3.0 / 4.0 / 5.0 |
| Milling Abutment | | 4.0 | 1.5 / 3.0 |
| Temporary Abutment | | 4.0 | 1.0 / 3.0 |
| Angled Abutment(17°) | | 4.0 / 4.5 | 2.0 / 4.0 |
| Ball Abutment | | 3.5 | 1.0 / 2.0 / 3.0 / 4.0 / 5.0 |

| Abutments | Material | Dia. (mm) | Height |
|---|---|---|---|
| Healing Abutment | Ti 6Al4V ELI, ASTM F136 | 4.3 / 4.8 | 3.0 / 4.0 / 5.0 / 7.0 / 9.0 |

- RP (Regular Platform) Connection Type Abutments

| Abutments | Material | Dia. (mm) | Gingival Height |
|---|---|---|---|
| Dual Abutment | Titanium Gr4, ASTM F67 | 4.6 / 5.0 / 6.0 | 1.0 / 2.0 / 3.0 / 4.0 / 5.0 |
| Combi Abutment | | 4.0 / 4.6 / 4.8 / 5.0 / 6.0 | 1.0 / 2.0 / 3.0 / 4.0 / 5.0 |
| Milling Abutment | | 4.0 / 5.0 / 6.0 | 1.5 / 3.0 |
| Temporary Abutment | | 4.5 | 1.0 / 3.0 |
| Angled Abutment(17°) | | 4.5 / 5.0 / 6.0 | 2.0 / 4.0 |
| Ball Abutment | | 3.5 | 1.0 / 2.0 / 3.0 / 4.0 / 5.0 |

| Abutments | Material | Dia. (mm) | Height |
|---|---|---|---|
| Healing Abutment | Ti 6Al4V ELI, ASTM F136 | 4.3 / 4.8 / 5.3 / 6.3 / 7.3 / 8.3 | 3.0 / 4.0 / 5.0 / 7.0 / 9.0 |

5.3. Cover Screw (Ti 6Al4V ELI, ASTM F136)

3.05mm Dia. x 5.25mm (L)
3.60mm Dia. x 5.88mm (L)

## 6. Indication for use:

Honorst Implant System is intended for use in partially or fully edentulous mandibles and maxilla, in support of single of multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. Honorst Implant System is for single stage and two stage surgical procedures. This system is intended for delayed loading.

## 7. Performance Data

The verification/validation testing activities were conducted on the subject device for the modifications made. The activities include identifying reference devices for external fixture design changes and a worst-case analysis of the subject device and primary predicate for fixture size and angled abutment modifications. The worst-case analysis demonstrated that the primary predicate remains the worst-case scenario with respect to fatigue testing. Sterilization, shelf life, endotoxin, and biocompatibility testing were not conducted since the materials, surface treatments, packaging, and sterilization have not changed from the primary predicate device (K160536) and the device modifications do not raise a concern for the worst case for these tests.

## 8. Substantial Equivalence

The Honorst Implant System has the same intended use as the identified predicate devices. They are similar in fundamental scientific technology in that they are all threaded, root form implants constructed of titanium SLA roughened surfaces. The subject and predicate fixtures are both bone-level implants that share similar body shape design such as straight walled neck and tapered body design. The modifications were made after the 510k clearance including fixture exterior design and size, but we found reference devices which encompasses the size range of the subject device with similar design.

The subject abutments are very similar to the predicate abutments that the medications are very minor which does not result in an issue to question substantial equivalence.

1. Fixture

| Item | Subject Device | Primary Predicate Device | Reference Predicate Devices | |
|---|---|---|---|---|
| 510(K) Number | K202039 | K160536 | K063341 | K121995 |
| Device Name | Honorst Implant System | CHAORUM Implant System | 3I OSSEOTITE CERTAIN DENTAL IMPLANTS | TS Fixture System |
| Manu-facturer | MEDIMECCA Co., Ltd. | MEDIMECCA Co., Ltd. | IMPLANT INNOVATIONS, INC. | OSSTEM Implant Co., Ltd. |
| Indications for Use | Honorst Implant System is intended for use in partially or fully edentulous mandibles and maxilla, in support of single of multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. Honorst Implant System is for single stage and two stage surgical procedures. This system is intended for delayed loading. | CHAORUM Implant System is intended for use in partially or fully edentulous mandibles and maxilla, in support of single of multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. CHAORUM Implant System is for single stage and two stage surgical procedures. This system is intended for delayed loading. | 3i dental implants are intended for surgical placement in the upper or lower jaw to provide a means for prosthetic attachment in single tooth restorations and in partially or fully edentulous spans with multiple single teeth, or as a terminal or intermediary abutment for fixed or removable bridgework, and to retain overdentures. In addition, when a minimum of 4 implants, >IOmni in length, are placed in the mandible and splinted in the anterior region, immediate loading is indicated. | The TS Fixture System is designed for dental implant surgery, it is placed on the maxillary or mandibular alveolar bone through a surgical procedure, and after osseointegration with the alveolar bone, it can replace a lost tooth by connecting the abutment post. The TS Fixture System is indicated for use in partially of 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. |

| | | | | |
|---|---|---|---|---|
| Design / Technological Characteristics | - Internal Hexagon connection<br>- Self-tapping cutting edge threads | - Internal Hexagon connection<br>- Self-tapping cutting edge threads | - Internal Hexagon connection<br>- Self-taping cutting edge threads | - Internal Hexagon connection<br>- Submerged Fixture<br>- Tapered body shape and straight body shape<br>- 4 sided cutting edge with self-tapping |
| Endosseous Implant Material | Titanium<br>(ASTM F67) | Titanium<br>(ASTM F136, ASTM F67) | Titanium<br>(ASTM F136, ASTM F67) | Titanium<br>(ASTM F67) |
| Surface Treatment | SLA | RBM,<br>SLA | SLA | SLA |
| Implant Sterilization Method | Radiation Sterile | Radiation Sterile | - | Radiation Sterile |
| Implant Diameters | 3.75-6.0mm | 3.25-6.0mm | 3.25-6.0mm | 3.5~6.8mm |
| Implant Lengths | 7.0-13.0mm | 7.3-15.0mm | 7.0-20.0mm | 7.0~15.0mm |

2. Abutments

| | Subject Device | Predicate Device |
|---|---|---|
| 510(K) Number | K202039 | K160536 |
| Device Name | Honorst Implant System | Chaorum Dental Implant System |
| Manufacturer | Medimecca Co., Ltd. | Medimecca Co., Ltd. |
| Indications for Use | Honorst Implant System is intended for use in partially or fully edentulous mandibles and maxilla, in support of single of multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. Honorst Implant System is for single stage and two stage surgical procedures. This system is intended for delayed loading. | CHAORUM Implant System is intended for use in partially or fully edentulous mandibles and maxilla, in support of single of multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. CHAORUM Implant System is for single stage and two stage surgical procedures. This system is intended for delayed loading. |
| Principle of Operation | - Internal Hexagon connection | - Internal Hexagon connection |
| Dual Abutment | | |
| Design & Size Range | Hex/Non-Hex<br>Diameter: 4.0~6.0mm<br>Gingival Height: 1.0~5.0mm<br>Angle: 0° | Hex/Non-Hex<br>Diameter: 3.5~6.5mm<br>Gingival Height: 1.0~5.5mm<br>Angle: 0° |
| Technological Characteristics | Screw retained restoration | Screw retained restoration |
| Material Composition | Ti Grade 4 (ASTM F67) | Ti Grade 4 (ASTM F67) |
| Surface Treatment | TiN Coating | TiN Coating |
| Sterile | No | No |
| Substantial Equivalence Discussion | The subject Dual Abutment is substantially equivalent to the predicate devices in terms of intended use and technical characteristics. They are made of the same material. There is a size option change, but the predicate device encompasses the size range of the subject device. | |

| Combi Abutment | | |
|---|---|---|
| Design & Size Range | Diameter: 4.0~6.0mm<br>Gingival Height: 1.0~5.0mm<br>Angle: 0° | Diameter: 3.5~6.5mm<br>Gingival Height: 1.0~5.5mm<br>Angle: 0° |
| Technological Characteristics | Abutment and screw in one-piece structure. | Abutment and screw in one-piece structure. |
| Material Composition | Ti Grade 4 (ASTM F67) | Ti Grade 4 (ASTM F67) |
| Surface Treatment | TiN Coating | TiN Coating |
| Sterile | No | No |
| Substantial Equivalence Discussion | The subject Combi Abutment is substantially equivalent to the predicate devices in terms of intended use and technical characteristics. They are made of the same material. There is a size option change, but the predicate device encompasses the size range of the subject device. | |
| Milling Abutment | | |
| Design & Size Range | Hex/Non-Hex<br>Diameter: 4.0~6.0mm<br>Gingival Height: 1.5~3.0mm<br>Angle: 0° | Hex/Non-Hex<br>Diameter: 3.5~6.5mm<br>Gingival Height: 1.0~3.5mm<br>Angle: 0° |
| Technological Characteristics | Screw retained restoration | Screw retained restoration |
| Material Composition | Ti Grade 4 (ASTM F67) | Ti Grade 4 (ASTM F67) |
| Surface Treatment | TiN Coating | TiN Coating |
| Sterile | No | No |
| Substantial Equivalence Discussion | The subject Milling Abutment is substantially equivalent to the predicate devices in terms of intended use and technical characteristics. They are made of the same material. There is a size option change, but the predicate device encompasses the size range of the subject device. | |
| Temporary Abutment | | |
| Design & Size Range | Hex/Non-Hex<br>Diameter: 4.0~4.5mm<br>Gingival Height: 1.0~3.0mm | Hex/Non-Hex<br>Diameter: 3.5~5.5mm<br>Gingival Height: 1.0~3.0mm |

| | | |
|---|---|---|
| | Angle: 0° | Angle: 0° |
| Technological Characteristics | Screw retained restoration | Screw retained restoration |
| Material Composition | Ti Grade 4 (ASTM F67) | Ti Grade 4 (ASTM F67) |
| Surface Treatment | No | No |
| Sterile | 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. There is a size option change, but the predicate device encompasses the size range of the subject device. | |
| Angled Abutment | | |
| Design & Size Range | Hex/Non-Hex<br>Diameter: 4.0~6.0mm<br>Gingival Height: 2.0, 4.0mm<br>Angle : 17˚ | Hex/Non-Hex<br>Diameter: 3.5~6.0mm<br>Gingival Height: 1.5~5.0mm<br>Angle : 15~25˚ |
| Technological Characteristics | Screw retained restoration | Screw retained restoration |
| Material Composition | Ti Grade 4 (ASTM F67) | Ti Grade 4 (ASTM F67) |
| Surface Treatment | TiN Coating | TiN Coating |
| 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. The angle has changed to 17° but it is within the range of the unmodified device. Also the location of TiN coating has changed but the difference is very minor not affecting substantial equivalence. | |
| Ball Abutment | | |
| Design & Size Range | Diameter: 3.5mm<br>Gingival Height: 1.0~5.0mm<br>Angle: 0° | Diameter: 3.5~4.0mm<br>Gingival Height: 1.0~5.0mm<br>Angle: 0° |
| Technological Characteristics | Abutment and screw in one-piece structure. | Abutment and screw in one-piece structure. |

| | | |
|---|---|---|
| Material Composition | Ti Grade 4 (ASTM F67) | Ti Grade 4 (ASTM F67) |
| Surface Treatment | TiN Coating | TiN Coating |
| Sterile | No | No |
| Substantial Equivalence Discussion | The subject Ball Abutment is substantially equivalent to the predicate devices in terms of intended use and technical characteristics. They are made of the same material. The size and the design are also the same. | |
| Healing Abutment | | |
| Design & Size Range | Diameter: 4.3~8.3mm<br>Gingival Height: 3.0~9.0mm<br>Angle: 0° | Diameter: 3.5~8.5mm<br>Gingival Height: 0~9.5mm<br>Angle: 0° |
| Technological Characteristics | Abutment and screw in one-piece structure. | Abutment and screw in one-piece structure. |
| Material Composition | Ti 6Al 4V ELI (ASTM F136) | Ti 6Al 4V ELI (ASTM F136) |
| Surface Treatment | Anodizing | No |
| Sterile | No | No |
| Substantial Equivalence Discussion | The subject Healing Abutment is substantially equivalent to the predicate devices in terms of intended use and technical characteristics. They are made of the same material. There is a size option change, but the predicate device encompasses the size range of the subject device. | |

## 9. Conclusion

The new device and the predicate device are substantially equivalent in the areas of technical characteristics, raw material, and design. The new device does not introduce a fundamentally new scientific technology, and the validation activities demonstrate that the subject device is substantially equivalent to the predicate device.