



Food and Drug Administration  
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Silver Spring, MD 20993-0002

SHINHUNG MST Co., Ltd.  
% Priscilla Chung  
Regulatory Affairs Consultant  
LK Consulting Group USA, Inc.  
800 Roosevelt Ste 417  
Irvine, California 92620

July 26, 2017

Re: K162867  
Trade/Device Name: MagDen Dental Implant System  
Regulation Number: 21 CFR 872.3640  
Regulation Name: Endosseous Dental Implant  
Regulatory Class: Class II  
Product Code: DZE, NHA  
Dated: June 28, 2017  
Received: June 29, 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 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 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,

  
Mary S. Runner -S

for

Lori Wiggins

Acting Director

Division of Anesthesiology,

General Hospital, Respiratory,

Infection Control, and Dental Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K162867

Device Name

MagDen Dental Implant System

Indications for Use (Describe)

The MagDen Dental Implant System is 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 patient's chewing function. The MagDen Fixture devices are specifically indicated for replacing maxillary lateral incisors and mandibular central and lateral incisors. The MagDen Fixture devices are indicated for immediate loading when good primary stability is achieved.

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**

(K162867)

July 26, 2017

### **1. Submitted by**

#### **SHINHUNG MST Co., Ltd**

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Contact: Sunbyung, Lee / Manager / Quality assurance team

### **2. US Agent**

Contact: Priscilla Chung (juhee.c@lkconsultinggroup.com)

LK Consulting Group USA, Inc.

800 Roosevelt STE 417, Irvine CA 92620

### **3. Device Name**

- Trade Name : MagDen Dental Implant System
- Common Names : Dental Implant
- Classification Name : Endosseous dental implant (CFR 872.3640)
- Product Codes : DZE (Primary), NHA

### **4. Predicate Device**

#### **4.1. Primary Predicate Device:**

IMTEC Sendax MDI and MDI Plus (K031106) by IMTEC Corporation

#### **4.2. Reference Predicate Device:**

- IMTEC MDI MII One-Piece Implant, 2.9mm (K081653) by IMTEC Corporation
- IMPLANTIUM PROSTHETICS (K052957) by Dentium Co., Ltd.
- Anker Dental Implant System - SB-III, ST and AT Series (K142557) by Alliance Global Technology Co., Ltd.
- MAGNA ABUTMENT (K984297) by FACTOR II, INC.

## 5. Device Description

The MagDen Dental Implant System offers MagDen Fixture, two abutment types (MagDen Mini Abutment, MagDen Abutment), MagDen Implant Healing Abutment, and MagDen Implant Cover Screw.

The MagDen Fixture provides both partially and completely edentulous patients with immediate masticatory function and it is made of Titanium alloy (ASTM F136, Ti-6Al-4V ELI) and S.L.A (Sand-Blasted, Large Grit, Acid-etched) is applied on the surface. MagDen Mini Abutment and MagDen Abutment are made of Stainless Steel (SUS444) and TiN coating is applied. All of the models of MagDen Mini Abutment and MagDen Abutment are intended for multiple-unit restorations only. MagDen Implant Healing Abutment and MagDen Implant Cover Screw are made of titanium alloy (ASTM F136, Ti-6Al-4V ELI) and no surface treatment for these components.

The size range of the subject fixture is as below.

- 2.2mm(D)×10.2, 11.7, 13.2, 14.7, 16.2mm(L)
- 2.7mm(D)×9.3, 10.0, 10.8, 11.5, 12.3, 13.0, 13.8, 14.5, 15.3, 16.0mm(L)
- 3.2mm(D)×9.3, 10.0, 10.8, 11.5, 12.3, 13.0, 13.8, 14.5, 15.3, 16.0mm(L)

The size ranges of the subject abutments are as below.

- Cover Screw: 2.676mm(D)×4.4mm(L), 2.56mm(D)×3.7mm(L)
- MagDen Mini Abutment: 3.8mm(D)×5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0mm(L)  
4.0mm(D)×4.3, 4.8, 5.3, 5.8, 6.3, 6.8, 7.3, 7.8mm(L)  
4.2mm(D)×5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0mm(L)
- MagDen Abutment: 4.8mm(D)×7.3, 7.8, 8.1, 8.3, 8.4, 8.5, 8.6, 8.8, 9.0, 9.1, 9.3, 9.4, 9.5, 9.6, 9.8, 10.0, 10.1, 10.3, 10.4, 10.5, 10.6, 10.8, 11.0, 11.1, 11.3, 11.4, 11.5, 11.6, 11.8, 12.0, 12.1, 12.3, 12.4, 12.5, 12.6, 12.8, 13.0, 13.1, 13.3, 13.4, 13.5, 13.6, 13.8, 14.0, 14.1, 14.3, 14.4, 14.5, 14.6, 14.8, 15.0, 15.1, 15.3, 15.4, 15.5, 15.8, 16.0, 16.1, 16.3, 16.4, 16.5, 16.8, 17.0, 17.1, 17.3, 17.4, 17.5, 18.0, 18.4, 18.5, 19.0mm(L)
- MagDen Implant Healing Abutment: 4.3mm(D)×5.0, 6.0, 7.0, 8.0, 9.0mm(L)  
4.5mm (D)×3.95, 4.8, 5.8, 6.8, 7.8mm(L)  
4.7mm (D)×5.0, 6.0, 7.0, 8.0, 9.0mm(L)

## 6. Indication For Use

The MagDen Dental Implant System is 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 patient's chewing function. The MagDen Fixture devices are specifically indicated for replacing maxillary lateral incisors and mandibular central and lateral incisors. The MagDen Fixture devices are indicated for immediate loading when good primary stability is achieved.

## 7. Substantial Equivalence

The MagDen Dental Implant System is substantially equivalent in intended use, design and performance to the predicated devices. There are slight differences in design but the fundamental technological characteristics between the devices are the same, and also the test results submitted herein support that the subject device is substantially equivalent to the predicate devices.

The indications for use include description for placement location and implant loading, which do not affect the intended use and are found substantially equivalent to the predicates.

### 7.1. Fixture

| Device Name               | Subject Device                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Primary Predicate Device                                                                                                                                                                                                                                                                                                                                                                                                     | Reference Predicate Device                                                                                                                                                                                                                                                                                                                                                                |
|---------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Manufacturer              | SHINHUNG MST Co., Ltd.                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | IMTEC Corporation                                                                                                                                                                                                                                                                                                                                                                                                            | IMTEC Corporation                                                                                                                                                                                                                                                                                                                                                                         |
| 510(k) Number             | -                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | K031106                                                                                                                                                                                                                                                                                                                                                                                                                      | K081653                                                                                                                                                                                                                                                                                                                                                                                   |
| Device Name               | MagDen Dental Implant System                                                                                                                                                                                                                                                                                                                                                                                                                                                              | IMTEC Sendax MDI and MDI Plus                                                                                                                                                                                                                                                                                                                                                                                                | IMTEC MDI MII One-Piece Implant, 2.9mm                                                                                                                                                                                                                                                                                                                                                    |
| Materials                 | Titanium alloy                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | Titanium alloy                                                                                                                                                                                                                                                                                                                                                                                                               | Titanium alloy                                                                                                                                                                                                                                                                                                                                                                            |
| Form                      | Endosseous dental implant                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Endosseous dental implant                                                                                                                                                                                                                                                                                                                                                                                                    | Endosseous dental implant                                                                                                                                                                                                                                                                                                                                                                 |
| Indications for use       | The MagDen Dental Implant System is 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 patient's chewing function. The MagDen Fixture devices are specifically indicated for replacing maxillary lateral incisors and mandibular central and lateral incisors. The MagDen Fixture devices are indicated for immediate loading when good primary stability is achieved. | The MDI and MDI PLUS are self-tapping titanium threaded screws indicated for long-term intra-bony applications. Additionally, the MDI may also be used for inter-radicular transitional applications. These devices will permit immediate splinting stability and long-term fixation of new or existing crown and bridge installations, for full partial edentulism, and employing minimally invasive surgical intervention. | The M11 Implant is intended to support single or multi-unit restorations in both long-term and temporary applications throughout the maxillary and mandibular arches. The MII implant is indicated for immediate loading when good primary stability is achieved. Additionally, this device will permit stability and long term fixation of upper and lower dentures in edentulous cases. |
| Technical characteristics | Screw Type<br>Internal Type                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Screw Type                                                                                                                                                                                                                                                                                                                                                                                                                   | Screw Type                                                                                                                                                                                                                                                                                                                                                                                |
| Sterilization             | Sterile<br>(Gamma Radiation)                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Sterile                                                                                                                                                                                                                                                                                                                                                                                                                      | Sterile                                                                                                                                                                                                                                                                                                                                                                                   |

|                              |                                                                                                                                                                                                                                                           |                                                                                                                                                                               |                                                                                     |
|------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|
| Shape                        |                                                                                                                                                                          |                                                                                              |  |
| Surface Treatment            | S.L.A                                                                                                                                                                                                                                                     | S.L.A                                                                                                                                                                         | S.L.A                                                                               |
| Dimension (Diameter, Length) | $\Phi 2.2(D) \times 10.2, 11.7, 13.2, 14.7, 16.2\text{mm}(L)$<br>$\Phi 2.7(D) \times 9.3, 10.0, 10.8, 11.5, 12.3, 13.0, 13.8, 14.5, 15.3, 16.0\text{mm}(L)$<br>$\Phi 3.2(D) \times 9.3, 10.0, 10.8, 11.5, 12.3, 13.0, 13.8, 14.5, 15.3, 16.0\text{mm}(L)$ | $\Phi 1.8(D) \times 10.0, 13.0, 15.0, 18.0\text{mm}(L)$<br>$\Phi 2.1(D) \times 10.0, 13.0, 15.0, 18.0\text{mm}(L)$<br>$\Phi 2.4(D) \times 10.0, 13.0, 15.0, 18.0\text{mm}(L)$ | $\Phi 2.9(D) \times 10.0, 13.0, 15.0, 18.0\text{mm}(L)$                             |
| Platform Diameter            | $\Phi 3.8, \Phi 4.0$                                                                                                                                                                                                                                      | $\Phi 2.7$                                                                                                                                                                    | $\Phi 2.9$                                                                          |

## 7.2. Abutments & Cover Screw

| Device Name   | Subject Device                        | Reference Predicate Device            | Reference Predicate Device                             | Reference Predicate Device            |
|---------------|---------------------------------------|---------------------------------------|--------------------------------------------------------|---------------------------------------|
| Manufacturer  | SHINHUNG MST Co., Ltd.                | Dentium Co., Ltd.                     | Alliance Global Technology Co., Ltd.                   | FACTOR II, INC.                       |
| 510(k) Number | -                                     | K052957                               | K142557                                                | K984297                               |
| Device Name   | MagDen Dental Implant System          | IMPLANTIUM PROSTHETICS                | Anker Dental Implant System - SB-III, ST and AT Series | MAGNA ABUTMENT                        |
| Materials     | Titanium alloy and stainless steel    | Titanium and titanium alloy           | Titanium alloy and stainless steel                     | Stainless steel                       |
| Form          | Abutment, Dental, Endosseous implants | Abutment, Dental, Endosseous implants | Abutment, Dental, Endosseous implants                  | Abutment, Dental, Endosseous implants |

|                     |                                                                                                                                                                                                                                              |                                                                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                |
|---------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Indications for use | <p>The MagDen Dental Implant System is 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 patient's chewing function.</p> | <p>Intended for use as an aid in prosthetic rehabilitation.</p> | <p>Anker Dental Implant System is intended to be surgically placed in the alveolar bone of upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, and to restore the patient's chewing function.</p> <p>Anker Dental Implant System is intended for delayed loading. No matter placing implants in anterior or posterior region, we recommend choosing the diameter of implants as large as possible. The prosthetic restorations used are single crowns, bridges and partial or full dentures, which are connected to the implants through the corresponding components (abutments). Specific indications for small diameter (3.3mm) and short (length &lt; 7mm) dental implants: Because of their reduced mechanical stability, small diameter and short implants are only used in cases with a low mechanical load. We recommend only used in the mandibular anterior region and maxillary</p> | <p>Magnacap is a magnetic abutment for implant retained dental and craniofacial prosthesis and root supported overdentures. Magnacap is engineered to fit several commercially available implant fixtures.</p> |
|---------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|



|                      |                                                                                                                                                                                                                               |                                                                                     |                  |                                                                                                  |
|----------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|------------------|--------------------------------------------------------------------------------------------------|
|                      |                                                                                                                                                                                                                               |                                                                                     | lateral incisor. |                                                                                                  |
| Cover Screw          |                                                                                                                                                                                                                               |                                                                                     |                  |                                                                                                  |
| Shape                |                                                                                                                                              |    | -                | -                                                                                                |
| Material             | Ti-6Al-4V ELI alloy                                                                                                                                                                                                           | Ti-6Al-4V ELI alloy                                                                 |                  |                                                                                                  |
| Size                 | $\Phi 2.676(D) \times 4.4\text{mm}(L)$<br>$\Phi 2.56(D) \times 3.7\text{mm}(L)$                                                                                                                                               | Dia. 3.50~4.28                                                                      | -                | -                                                                                                |
| MagDen Mini Abutment |                                                                                                                                                                                                                               |                                                                                     |                  | Magna Abutment                                                                                   |
| Shape                |                                                                                                                                              |    | -                |               |
| Material             | SUS444                                                                                                                                                                                                                        | Ti-Gr4                                                                              |                  | Stainless steel                                                                                  |
| Size                 | $\Phi 3.8(D) \times 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0\text{mm}(L)$<br>$\Phi 4.0(D) \times 4.3, 4.8, 5.3, 5.8, 6.3, 6.8, 7.3, 7.8\text{mm}(L)$<br>$\Phi 4.2(D) \times 5.5, 6.0, 6.5, 7.0, 7.5, 8.0, 8.5, 9.0\text{mm}(L)$ | Dia.4.5~5.5                                                                         | -                | $\Phi 4.4(D) \times 3.5, 3.6, 5.5\text{mm}(L)$<br>$\Phi 5.1(D) \times 2.1, 3.5, 5.5\text{mm}(L)$ |
| MagDen Abutment      |                                                                                                                                                                                                                               |                                                                                     |                  |                                                                                                  |
| Shape                |                                                                                                                                            |  | -                | -                                                                                                |
| Material             | SUS444                                                                                                                                                                                                                        | Ti-Gr4                                                                              |                  |                                                                                                  |
| Size                 | $\Phi 4.8(D) \times 7.3, 7.8, 8.1, 8.3, 8.4, 8.5, 8.6, 8.8, 9.0, 9.1, 9.3, 9.4, 9.5, 9.6, 9.8, 10.0, 10.1, 10.3, 10.4, 10.5, 10.6, 10.8, 11.0, 11.1, 11.3, 11.4,$                                                             | Dia.4.5~5.5                                                                         | -                | -                                                                                                |

|                                 |                                                                                                                                                                                                                                                                                                                                |                                                                                   |   |   |
|---------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------|---|---|
|                                 | 11.5, 11.6, 11.8,<br>12.0, 12.1, 12.3,<br>12.4, 12.5, 12.6,<br>12.8, 13.0, 13.1,<br>13.3, 13.4, 13.5,<br>13.6, 13.8, 14.0,<br>14.1, 14.3, 14.4,<br>14.5, 14.6, 14.8,<br>15.0, 15.1, 15.3,<br>15.4, 15.5, 15.8,<br>16.0, 16.1, 16.3,<br>16.4, 16.5, 16.8,<br>17.0, 17.1, 17.3,<br>17.4, 17.5, 18.0,<br>18.4, 18.5,<br>19.0mm(L) |                                                                                   |   |   |
| MagDen Implant Healing Abutment |                                                                                                                                                                                                                                                                                                                                |                                                                                   |   |   |
| Shape                           |                                                                                                                                                                                                                                               |  | - | - |
| Material                        | Ti-6Al-4V ELI alloy                                                                                                                                                                                                                                                                                                            | Ti-Gr4                                                                            | - | - |
| Size                            | $\Phi 4.3(D) \times 5.0, 6.0, 7.0, 8.0, 9.0\text{mm(L)}$<br>$\Phi 4.5 \times 3.95, 4.8, 5.8, 6.8, 7.8\text{mm(L)}$<br>$\Phi 4.7(D) \times 5.0, 6.0, 7.0, 8.0, 9.0\text{mm(L)}$                                                                                                                                                 | Dia.4.5~6.5                                                                       | - | - |

## 8. Performance Testing

- Biocompatibility Tests

Biocompatibility testing on the proposed MagDen Dental Implant System has been completed. Requirements for biological evaluation of the proposed device were based on the ISO 7405(2008), “Dentistry-Evaluation of biocompatibility of medical devices used in dentistry.” The biocompatibility test results show that the materials used in the design and manufacture of the components of the proposed device are non-toxic and non-sensitizing to biological tissues consistent with its intended use. The following biocompatibility tests were completed.

- Fixtures, Healing Abutments, Screws

| No. | Item                        | Referenced Standard | Results                    |
|-----|-----------------------------|---------------------|----------------------------|
| 1   | Cytotoxicity                | ISO10993-5          | No cytotoxicity            |
| 2   | Genotoxicity                | ISO10993-3          | No genotoxicity            |
| 3   | Skin sensitization reaction | ISO10993-10         | No sensitization           |
| 4   | Intradermal reactivity      | ISO10993-10         | No intradermal reactivity  |
| 5   | Acute systemic toxicity     | ISO10993-11         | No acute systemic toxicity |
| 6   | Pyrogenicity                | USP37 <151>         | No pyrogenicity            |
| 7   | Transplantation             | ISO10993-6          | No subchronic toxicity     |
| 8   | Subchronic toxicity         | ISO10993-11         | No subchronic toxicity     |

- Abutments

| No. | Item                        | Referenced Standard | Results                |
|-----|-----------------------------|---------------------|------------------------|
| 1   | Genotoxicity                | ISO10993-3          | No genotoxicity        |
| 2   | Transplantation             | ISO10993-6          | No subchronic toxicity |
| 3   | Subchronic toxicity         | ISO10993-11         | No subchronic toxicity |
| 4   | Delayed hypersensitivity    | ISO10993-10         | No sensitization       |
| 5   | Cytotoxicity                | ISO10993-5          | No cytotoxicity        |
| 6   | Oral mucosa irritation test | ISO10993-10         | No irritation          |

- Performance Tests

The proposed devices were evaluated as below to support the substantial equivalence to the predicate devices.

- Fixture

The following performance tests were conducted for the Fixture devices and found to meet the acceptance criteria for demonstrating substantial equivalence: Appearance, Dimensions, Detailed Fitness, and Package integrity.

- Abutments

The following performance tests were conducted for the Abutments and found to meet the acceptance criteria for demonstrating substantial equivalence: Appearance, Dimensions, Package integrity, Loosening Torque, Rotational Shear Strength, Retention Force, Detailed Fitness, Surface characteristics, and Galvanic Corrosion.

- **Sterilization Validation Tests**  
Sterilization validation tests were performed for the fixture and the abutment devices in accordance with the referenced standards below.
- **Fixtures**  
To verify the sterility assurance level (10<sup>-6</sup>) for gamma sterilization procedure for MagDen Fixtures, the validation and biological indicator (BI) overkill method was used in accordance to ISO 11137-1, 2, 3 and ISO 11737-1, 2, 3.
- **Abutments**  
To verify the sterility assurance level (10<sup>-6</sup>) for the steam sterilization procedure for MagDen Abutments, the validation and biological indicator (BI) overkill method was used in accordance to ANSI/AAMI ST81, ANSI/AAMI ST79, ANSI/AAMI/ISO 17665-1, ANSI/AAMI/ISO 17665-2, AAMI TIR39, AAMI TIR No. 12.
- **Surface Treatment Evaluations**  
Bench testing of the SLA modified surface treatment of the fixture devices, and bench testing of the TiN coating modified surface treatment of the abutment devices were performed and the test results support that the surface treatments do not raise a question.
- **Fixtures**  
SLA surface cleaning effectiveness tests and surface analysis after the cleaning were performed by various testing methods verified that the chemical agents used to remove particles have been washed from the surface and shows there is no blasting media particles remaining.
- **Abutments**  
Coating porosity, mean volume percent of voids, surface roughness of the coating, and scanning electron microscopy evaluations were performed to evaluate the TiN coating of the subject device, and the test results support that the TiN coating does not raise a question.

## **9. Conclusion**

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification, SHINHUNG MST Co., Ltd concludes that the MagDen Dental Implant System is substantially equivalent to the predicate devices as described herein.