DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

January 5, 2017

Medimecca Co., Ltd.
% Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Inc.
800 Roosevelt Ste 417
Irvine, California 92606

Re: K160536
Trade/Device Name: Chaorum Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: December 6, 2016
Received: December 8, 2016

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 yours,

Michael J. Ryan -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K160536

Device Name
Chaorum Implant System

Indications for Use *(Describe)*

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.

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

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

Date: 12/06/2016

1. Applicant / Submitter

	Submitter
Name	Medimecca Co., Ltd.
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Phone	+82-2-856-8282
Fax	+82-2-856-0238
Contact	Park Young Wan, QMR

2. U.S Agent/Contact Person

Priscilla Chung
LK Consulting Group USA, Inc.
800 Roosevelt Ste 417, Irvine CA 92606
Phone: 714.202.5789 Fax: 714-409-3357
Email: juhee.c@lkconsultinggroup.com

3. Device

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

4. Predicate Device:

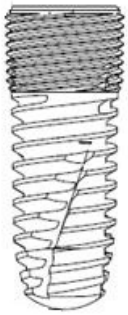
- **Primary Predicate Device:**
  UD Implant System by MEDIMECCA Co., Ltd. (K131682)
- **Reference Predicate Device:**
  Hahn Tapered Implant System by PRISMATIK DENTALCRAFT, INC (K143353)
  JDentalCare Implant System by J DENTAL CARE S.r.l.. (K143142)

IDI Implant Systems by IDI BIOMEDICAL LLC (K081806)
NobelActive® by NOBEL BIOCARE USA, LLC (K142260)
3I OSSEOTITE CERTAIN DENTAL IMPLANTS by IMPLANT INNOVATIONS, INC. (K063341)

5. Description:

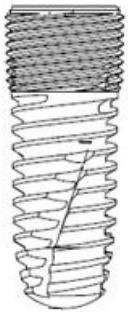
Chaorum Implant System are devices made of titanium intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices such as artificial teeth, and to restore the patients chewing function. Chaorum Implant System consists of fixtures, abutments, and screws. Its material, structure and intended use are substantially equivalent to the predicate devices. It offers three different implants in RBM treatment and SLA treatment.

5.1. Fixtures –RBM (Titanium 6AL4V, ASTM F136)

Shape	Size
 SFB Model Series	NP (Narrow Platform) Connection Type Fixture 3.25mm Dia. x 8.0mm(L) / 8.5mm (L) / 10.0mm(L) / /12.0mm(L) /14.0mm(L) / 15.0mm(L) 3.89mm Dia. x 8.0mm(L) /10.0mm(L) / 12.0mm(L) / 14.0mm(L) RP (Regular Platform) Connection Type Fixture 3.89mm Dia. x 8.0mm(L) /10.0mm(L) / 12.0mm(L) / 14.0mm(L) 4.28mm Dia. x 8.0mm(L) /10.0mm(L) / 12.0mm(L) / 14.0mm(L) 4.78mm Dia. x 8.0mm(L) /10.0mm(L) / 12.0mm(L) / 14.0mm(L) 5.28mm Dia. x 8.0mm(L) /10.0mm(L) / 12.0mm(L) / 14.0mm(L) 6.28mm Dia. x 8.0mm(L) /10.0mm(L) / 12.0mm(L) / 14.0mm(L)
 ASFS Model Series	NP (Narrow Platform) Connection Type Fixture 3.25mm Dia. x 8.0mm(L) / 8.5mm (L) / 10.0mm(L) / /12.0mm(L) /14.0mm(L) 3.89mm Dia. x 8.0mm(L) /10.0mm(L) / 12.0mm(L) / 14.0mm(L) RP (Regular Platform) Connection Type Fixture 3.89mm Dia. x 8.0mm(L) /10.0mm(L) / 12.0mm(L) / 14.0mm(L) 4.28mm Dia. x 8.0mm(L) /10.0mm(L) / 12.0mm(L) / 14.0mm(L) 4.78mm Dia. x 8.0mm(L) /10.0mm(L) / 12.0mm(L) / 14.0mm(L) 5.28mm Dia. x 8.0mm(L) /10.0mm(L) / 12.0mm(L) / 14.0mm(L) 6.28mm Dia. x 8.0mm(L) /10.0mm(L) / 12.0mm(L) / 14.0mm(L)
 MSF Model	NP (Narrow Platform) Connection Type Fixture 3.25mm Dia. x 8.5mm (L) / 10.0mm(L) / 11.50mm(L) /13.0mm(L) 3.75mm Dia. x 8.5mm (L) / 10.0mm(L) / 11.50mm(L) /13.0mm(L) / 15.0mm(L) RP (Regular Platform) Connection Type Fixture 4.30mm Dia. x 7.3mm(L) /8.5mm(L) / 10.0mm(L) / 11.5mm(L)/ 13.0mm(L) / 15.0mm(L) 4.50mm Dia. x 7.3mm(L) /8.5mm(L) / 10.0mm(L) / 11.5mm(L)/ 13.0mm(L) / 15.0mm(L)

Series	5.00mm Dia. x 7.3mm(L) /8.5mm(L) / 10.0mm(L) / 11.5mm(L)/ 13.0mm(L) / 15.0mm(L) 6.00mm Dia. x 7.3mm(L) /8.5mm(L) / 10.0mm(L) / 11.5mm(L)/ 13.0mm(L) / 15.0mm(L)

5.2. Fixtures --SLA(Titanium Gr 4, ASTM F67)

Shape	Size
 ASF Model Series	NP (Narrow Platform) Connection Type Fixture 3.25mm Dia. x 8.0mm(L) / 8.5mm (L) / 10.0mm(L) / /12.0mm(L) /14.0mm(L) / 15.0mm(L)/15.5mm(L) 3.89mm Dia. x 8.0mm(L) /10.0mm(L) / 12.0mm(L) / 14.0mm(L) RP (Regular Platform) Connection Type Fixture 3.89mm Dia. x 8.0mm(L) /10.0mm(L) / 12.0mm(L) / 14.0mm(L) 4.28mm Dia. x 8.0mm(L) /10.0mm(L) / 12.0mm(L) / 14.0mm(L) 4.78mm Dia. x 8.0mm(L) /10.0mm(L) / 12.0mm(L) / 14.0mm(L) 5.28mm Dia. x 8.0mm(L) /10.0mm(L) / 12.0mm(L) / 14.0mm(L) 6.28mm Dia. x 8.0mm(L) /10.0mm(L) / 12.0mm(L) / 14.0mm(L)
 ATF Model Series	NP (Narrow Platform) Connection Type Fixture 3.89mm Dia. x 8.0mm(L) /10.0mm(L) / 12.0mm(L) / 14.0mm(L) RP (Regular Platform) Connection Type Fixture 3.89mm Dia. x 8.0mm(L) /10.0mm(L) / 12.0mm(L) / 14.0mm(L) 4.28mm Dia. x 8.0mm(L) /10.0mm(L) / 12.0mm(L) / 14.0mm(L) 4.78mm Dia. x 8.0mm(L) /10.0mm(L) / 12.0mm(L) / 14.0mm(L) 5.28mm Dia. x 8.0mm(L) /10.0mm(L) / 12.0mm(L) / 14.0mm(L) 6.28mm Dia. x 8.0mm(L) /10.0mm(L) / 12.0mm(L) / 14.0mm(L)
 PSF Model Series	NP (Narrow Platform) Connection Type Fixture 3.75mm Dia. x 8.5mm (L) / 10.0mm(L) / 11.50mm(L) /13.0mm(L) / 15.0mm(L) RP (Regular Platform) Connection Type Fixture 4.30mm Dia. x 7.3mm(L) /8.5mm(L) / 10.0mm(L) / 11.5mm(L)/ 13.0mm(L) / 15.0mm(L) 4.50mm Dia. x 7.3mm(L) /8.5mm(L) / 10.0mm(L) / 11.5mm(L)/ 13.0mm(L) / 15.0mm(L) 5.00mm Dia. x 7.3mm(L) /8.5mm(L) / 10.0mm(L) / 11.5mm(L)/ 13.0mm(L) / 15.0mm(L) 6.00mm Dia. x 7.3mm(L) /8.5mm(L) / 10.0mm(L) / 11.5mm(L)/ 13.0mm(L) / 15.0mm(L)

5.3. Abutments

- NP (Narrow Platform) Connection Type Two Piece Abutments

Abutments		Material	Dia(mm)
Dual Abutment		Titanium Gr 4 ASTM F 67 / TiN Coating	3.5/ 4.0/ 4.5
Combi Abutment			3.5/ 4.0/ 4.5
Angled Abutment (15° ,17°, 25°)	MSAA--		3.5/4.0/4.5
	CSAA--		3.5/4.0/4.5
Billow Abutment			3.5/ 4.0/ 4.5
Temporary Abutment			3.5/ 4.0/ 4.5
Ball Abutment			3.5/4.0
Healing Abutment		Ti6AL4V ELI, ASTM F 136	3.5/4.0/4.5

- RP (Regular Platform) Connection Type Two Piece Abutments

Abutments		Material	Dia(mm)
Dual Abutment		Titanium Gr 4 ASTM F 67 / TiN Coating	4.5/5.0/5.5/6.0/6.5
Combi Abutment			4.5/5.0/5.5/ 6.0/6.5
Angled Abutment (15° ,17°, 25°)	MSAA--		4.5/5.0/5.5/6.0
	CSAA--		4.5/5.0/5.5/6.0
Billow Abutment			4.5/5.0/5.5/6.0/6.5
Temporary Abutment			4.5/5.0/5.5
Ball Abutment			3.5/4.0
Healing Abutment		Ti6AL4V ELI, ASTM F 136	4.0/4.5/5.0/5.5/6.0/ 6.5/7.5/8.5

5.4. Cover Screws (Ti6AL4V ELI, ASTM F 136)

1.95mm Dia. x 5.8mm (L) / 6.5mm(L)

6. Indication for use:

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.

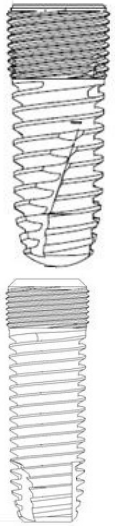
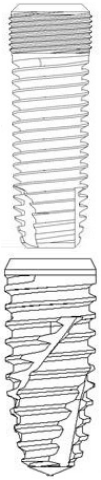
7. Basis for Substantial Equivalence

The Chaorum Dental 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 with RBM or SLA roughened surfaces. The subject and predicate devices are both bone-level implants that share similar body shape design such as straight walled neck and tapered body design.

The subject and predicate devices are similar in size, materials, surface treatment, and are sterilized via gamma irradiation for fixtures.

Item	**Subject Device**	**Primary Predicate Device**	**Reference Predicate Devices**				
510(K) Number	-	K131682	K143353	K143142	K081806	K142260	K063341
Device Name	Chaorum Implant System	UD Implant System	Hahn Tapered Implant System	JDentalCare Implant System	IDI Implant Systems	NobelActive®	3I OSSEOTITE CERTAIN DENTAL IMPLANTS
Manufacturer	MEDIMECCA Co., Ltd.	MEDIMECCA Co., Ltd.	PRISMATIK DENTALCRAFT, INC	J DENTAL CARE S.r.l..	IDI BIOMEDICAL LLC	NOBEL BIOCARE USA, LLC	IMPLANT INNOVATIONS, INC.
Indications for Use	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	UD Implant System is intended for use in partially or fully edentulous mandibles and maxilla, in support of single of multiple-unit restorations including;	Hahn Implants are indicated for use in maxillary and mandibular partially or fully edentulous cases, to support single, multiple-unit, and overdenture restorations. The implants are to be used for immediate loading only in the presence of	JDentalCare® implant system is intended for surgical placement in the upper or lower jaw. JDentalCare® implant system is comprised of dental implant fixtures and prosthetic	IDI Implant Systems (IDI Fixtures and IDI Abutments with screws) are endosseous implants intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic	NobelActive® implants are endosseous implants intended to be surgically placed in the upper or lower jaw bone for anchoring or supporting tooth replacements to restore patient	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

	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.	cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. UD Implant System is for single stage and two stage surgical procedures. This system is intended for delayed loading.	primary stability and appropriate occlusal loading	devices. JDentalCare® implant system provides a means for prosthetic attachment in single tooth restorations and partially or fully edentulous spans with multiple single teeth utilizing delayed or immediate loading, or as a terminal or intermediary abutment for fixed or removable bridgework or to retain overdentures. Prosthetic devices provide support and retention for screwretained or cemented restorations in mandible and maxilla. JDentalCare®	devices, such as an artificial tooth, in order to restore patient esthetics and chewing function. Straight abutments indicated for both screw retained and cemented restorations are included. The implants are indicated for single or multiple unit restorations and can be used in splinted and non-splinted applications. The device is intended for immediate loading when good primary stability has been achieved and with appropriate occlusal loading.	esthetics and chewing function. NobelActive® implants are indicated for single or multiple unit restorations in splinted or non-splinted applications. This can be achieved by a 2-stage or 1-stage surgical technique in combination with immediate, early or delayed loading protocols, recognizing sufficient primary stability and appropriate occlusal loading for the selected technique. NobelActive® 3.0 implants are intended to replace a lateral incisor	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.

				implant system is intended for immediate function on single tooth and/or multiple tooth applications when good primary stability is achieved, with appropriate occlusal loading, in order to restore chewing function.		in the maxilla and/or a central or lateral incisor in the mandible. NobelActive® 3.0 implants are indicated for single unit restorations only.	
Design/Principle of Operation				- Internal Hexagon connection - Self-taping cutting edge threads		- Endomaxim Internal Connection - Implant threads allow self drilling		- Internal Hexagon connection - Self-taping cutting edge threads	

	 - Internal Hexagon connection - Self-taping cutting edge threads	- Internal Hexagon connection - Self-taping cutting edge threads	- Internal Hexagon connection - Self-taping cutting edge threads				- Internal Hexagon connection - Self-taping cutting edge threads
Endosseous Implant Material	Titanium (ASTM F136, ASTM F67)	Titanium (ASTM F136, ASTM F67)	Titanium (ASTM F136, ASTM F67)	Titanium (ASTM F136, ASTM F67) Ti Gr. 5 for Ø 3,25mm	Titanium	CP Titanium	Titanium (ASTM F136, ASTM F67)
Surface Treatment	RBM, SLA	RBM	RBM	SLA	RBM	TiUnite	SLA
Implant Sterilization Method	Radiation Sterile	Radiation Sterile	Radiation Sterile	Radiation Sterile	-	Radiation Sterile	-
Implant Diameters	3.25-6.0mm	3.5-6.0mm	3.0-7.0mm	3.25-6.0mm	3.5-6.0mm	3.0-5.5mm	3.25-6.0mm
Implant Lengths	7.3-15.0mm	7.3-15.0mm	8.0-16.0mm	8.0-15.0mm	8.8-16.0mm	7.0-18.0mm	7.0-20.0mm
Angulations of Angled abutments	15°, 17°, 25°	15°, 25°	15° ~ 30°	0° ~ 30°	15°	0°~30°	0-25°
Abutments Diameters	3.5-6.0mm	4.0-6.0mm	3.0-7.0mm	3.2-6.0mm	-	3.6-6.0mm	3.4-7.5
Abutments Materials	- Ti-6Al-4V ELI - Titanium Gr	-Ti-6Al-4V ELI - Titanium Gr 4	Ti-6Al-4V ELI	Ti-6Al-4V ELI	Ti-6Al-4V ELI	Ti-6Al-4V ELI	Ti-6Al-4V ELI

	4 ASTM F 67	ASTM F 67					

8. Non-Clinical Testing

The following non-clinical testing was conducted to validate its safety.

- Physical tests including visual test, packaging test, packaging seal efficacy test, dimension test, and sterility test (direct transfer method)
- RBM/SLA Surface treatment tests including roughness average test, developed surface area ration test, surface characteristics test (SEM), and surface composition analysis test (EDX)
- TiN coating tests including surface roughness and abrasion testing
- Mechanical properties test including adaptation accuracy test (Implant to abutment compatibility), 35° compressive loads test, torsional breaking force test, removal torque force test, and fatigue test
- Sterilization validation and shelf life tests
- The following biocompatibility tests have been performed in accordance with ISO10993 series.

No	Test Title	Test Standard
1	Cytotoxicity Test	ISO10993-5:2009
2	Acute Systemic Toxicity Test	ISO10993-11:2006
3	Intracutaneous Reactivity Test	ISO10993-10:2010
4	Pyrogen Test	ISO10993-11:2006
5	Local Lymph Node Assay, LLNA Test	ISO10993-10:2010
6	Bone Implantation Test	ISO10993-6:2007

9. Conclusion

Based on the similarities and the test results of the validation activities, we conclude that the Chaorum Dental Implant System is substantially equivalent to the predicate device.