October 26, 2018

Biomate Medical Devices Technology Co., Ltd.
Leslie Su
Assistant Manager
1F., No.59, Luke 2nd Road, Luzhu District
Kaohsiung City, 820
TAIWAN (R.O.C)

Re: K170732
Trade/Device Name: Biomate Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: September 21, 2018
Received: September 28, 2018

Dear Leslie Su:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K170732

Device Name
Biomate Dental Implant System

Indications for Use *(Describe)*
An endosseous dental implant is indicated for surgical placement in the upper and lower jaw arches, to provide a root form means for single or multiple unit prosthetic appliance attachment to restore a patient's chewing function. Implants can be placed with a conventional 2 stage surgical process with an option for transmucosal healing or they can be placed in a single stage surgical process for immediate loading. It is intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Patients must be subject for dental treatment with endosseous implants.

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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Biomate Dental Implant System

K170732

1. Date Prepared

2018-10-26

2. Submitter's Information

Company Name:	Biomate Medical Devices Technology Co., Ltd.
Company Address:	1F., No.59, Luke 2nd Rd., Luzhu Dist, Kaohsiung City, 820, Taiwan, R. O. C
Contact Person:	Leslie Su
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Fax:	+886-7-621-3163
Email:	leslie.su@shanyin.com.tw

3. Trade Name, Common Name, Classification

Trade or Proprietary Name:	Biomate Dental Implant System
Common Name:	Implant, Endosseous Root-Form
Subsequent Common Name:	Abutment, Implant, Dental, Endosseous
Classification Name:	Endosseous dental implant
Subsequent Classification Name:	Endosseous dental implant abutment
Regulation Number:	21 CFR 872.3640
Product Code:	DZE
Subsequent Product Code	NHA
Class of Device:	Class II
Panel:	Dental

4. Legally Marketed Predicate Device(s)

4.1 Primary Predicate

510(k) Number:	K142174
Applicant:	BIOMATE MEDICAL DEVICES TECHNOLOGY CO., LTD.
Device Name:	BIOMATE DENTAL IMPLANT SYSTEM

4.2 Reference Predicate

510(k) Number:	K171694
Applicant:	Dentis Co., Ltd.
Device Name:	s-Clean TiN Abutments

5. Device Description

The Biomate Dental Implant System consists of Bone Type Implant Plus, Shaping Abutment and Healing Abutment. The Biomate Dental Implant System is made of commercial pure titanium (ASTM F67, Grade 4). Threaded dental implants are with Precision Dimension Laser (PDL™) surface treatment, while Shaping Abutment and Healing Abutment are with TiN coated surface treatment. The device is designed for conventional two-stage and single stage procedures for single and multiple unit prosthetics. It is intended to be used to replace missing teeth.

6. Indication for Use Statement

An endosseous dental implant is indicated for surgical placement in the upper and lower jaw arches, to provide a root form means for single or multiple unit prosthetic appliance attachment to restore a patient's chewing function. Implants can be placed with a conventional 2 stage surgical process with an option for transmucosal healing or they can be placed in a single stage surgical process for immediate loading. It is intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Patients must be subject for dental treatment with endosseous implants.

7. Technological Characteristics

The Biomate Dental Implant System consists of Bone Type Implant Plus, Shaping Abutment and Healing Abutment. The device is made of commercial pure titanium (ASTM F67, Grade 4).

» Bone Type Implant Plus comes with PDL™ surface treatment and consists a set of threaded, root-form, bone level implants offered in 3.5, 4.0, 4.5mm diameters (D) with 8, 10, 12, 14mm length (L).

- »Shaping Abutment comes with TiN coated surface treatment via Physical Vapor Deposition (PVD) process and consists a set of abutments offered in 4.0, 5.0, 6.0mm diameters (D) with 11.0mm height (H), and 1.5, 3.0 mm Gingival Height (G/H)
- » Healing Abutment comes with TiN coated surface treatment via Physical Vapor Deposition (PVD) process and consists a set of abutments offered in 4.0, 4.5, 5.0, 6.0mm diameters (D) with 2.0, 3.0, 5.0, 7.0mm height (H), and 1.0, 2.0, 3.0 mm Gingival Height (G/H)

The subject device is compatible with our previous cleared device submission (K142174).

The subject device is provided sterile (Radiation) and for single use only.

8. Substantial Equivalence

The following table compares the Biomate Dental Implant System to the predicate device with respect to indications for use, principles of operation, technological characteristics, materials, and performance testing. The comparison of the devices provides more detailed information regarding the basis for the determination of substantial equivalence. Comparative data is shown in Table 5-1.

Table 2-1 Substantial Equivalence Comparison

--	Subject device	Primary Predicate	Reference predicate
Manufacturer	Biomate Medical Devices Technology Co., Ltd.	Biomate Medical Devices Technology Co., Ltd.	Dentis Co., Ltd
Device Name	Biomate Dental Implant System	Biomate Dental Implant System	s-Clean TiN Abutments
510(k) Number	K170732	K142174	K171694
Product Code	DZE	DZE	NHA
Regulation Number	872.3640	872.3640	872.3630
Regulation Name	Endosseous dental implant	Endosseous dental implant	Endosseous dental implant abutment
Prescription use	YES	YES	YES
Indications for Use	An endosseous dental implant is indicated for surgical placement in the upper and lower jaw arches, to provide a root form means for single or multiple unit prosthetic appliance attachment to restore a patient's chewing function. Implants can be placed with a conventional 2 stage surgical process with an option for transmucosal healing or they can be placed in a single stage surgical process for immediate loading. It is intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Patients must be subject for dental treatment with endosseous implants.	An endosseous dental implant is indicated for surgical placement in the upper and lower jaw arches, to provide a root form means for single or multiple unit prosthetic appliance attachment to restore a patient's chewing function. Implants can be placed with a conventional 2 stage surgical process with an option for transmucosal healing or they can be placed in a single stage surgical process for immediate loading. It is intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Patients must be subject for dental treatment with endosseous implants.	The s-Clean TiN Coating Abutments is an endosseous dental implant that is indicated for surgical placement in the upper and lower jaw arches, to provide a root form means for single or multiple-units prosthetic appliance attachment to restore a patient’s chewing function. Implants can be place with a conventional two stage surgical process with an option for transmucosal healing or they can be placed in a single stage surgical process for immediate loading when good primary stability has been achieved and with appropriate occlusal loading.
Consisted Instrument	Dental Implants, Abutments	Dental Implants, Abutments, screws	Abutments
Sterilization	Gamma irradiation	Gamma irradiation	Non-sterile

Implant Material	Grade 4 Pure Titanium per ASTM F67	Grade 4 Pure Titanium per ASTM F67	Not applicable
Implant Type	Threaded, Root-form, Bone level	Threaded, Root-form, Bone level	Not applicable
Implant to Abutment Connection	Internal Hex	Internal Hex	Not applicable
Implant Diameter (mm)	3.5, 4.0, 4.5	3.3, 4.1, 4.8, 5.5	Not applicable
Implant Length (mm)	8, 10, 12, 14	8, 10, 12, 14	Not applicable
Implant Surface Treatment	PDL™ surface treatment	PDL™ surface treatment	Not applicable
Abutment System	Healing Abutment, Shaping Abutment	Healing Abutment, Solid Abutment, Simple Abutment, 15°/ 25° Angled Abutment, Temporary Abutment, Ball Abutment	s-Clean TiN Half Coating FreeMill Abutment
Abutment Material	Grade 4 Pure Titanium per ASTM F67	Grade 4 Pure Titanium per ASTM F67	Pure Titanium (Grade 4)
Abutment Angle (°)	0	0, 15, 25	Not available
Platform Diameter (mm)	4.0, 4.5, 5.0, 6.0	4.0, 4.5, 5.0, 6.0	4.0, 4.5, 5.5, 6.5, 7.5
Platform Length (mm)	2.0, 3.0, 5.0, 7.0	3.0, 5.0, 7.0	1.3, 1.8, 2.8, 3.8
Platform Gingival Height (mm)	1.0, 1.5, 2.0, 3.0	0.5,1.0, 2.0, 3.0 ,4.0	Not available
Abutment Surface Treatment	TiN coated surface treatment	N/A	TiN coating by physical vapor deposition (PVD)

9. Summary of Non-clinical Tests

Biomate Dental Implant System and in showing substantial equivalence to the predicate devices that are subject to this 510(k) submission, we completed a number of non-clinical performance tests. The Biomate Dental Implant System meets all the requirements for overall design, sterilization, biocompatibility, electrical safety results and the recommendations in “Class II Special Controls Guidance Document: Root-form Endosseous Dental Implant and Endosseous Dental Implant

Abutments" confirming that the design output meets the design inputs and specifications for the device.

The Biomate Dental Implant System passed all the testing in accordance with internal requirements, national standards, and international standards shown below to support substantial equivalence of the subject device:

- Biocompatibility Testing referenced in K142174 per ISO 10993-1, ISO 10993-3, ISO 10993-5, ISO 10993-6, ISO 10993-10, ISO 10993-11, ISO 10993-12
- Sterilization testing referenced in K142174 per ISO 11137-1, ISO 11137-2, ISO 11737-1, ISO 11737-2
- Fatigue testing referenced in K142174 per ISO 14801
- Shelf-Life testing referenced in K142174 per ISO 11607
- LAL testing according to United States Pharmacopeial Convention, Inc. USP <85>

10. Clinical Tests

There was no human clinical testing required to support the medical device as the indications for use is equivalent to the predicate device. The non-clinical testing detailed in this submission supports the substantial equivalence of the device.

11. Conclusion

The Biomate Dental Implant System as designed and manufactured, is determined to be substantially equivalent to the referenced predicate device.