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

April 25,2016

Taiwan Implant Technology Company, Ltd.
Kaohsiung Science Park Branch
Huang Ching-Chieh
Assistant Manager
5f., No.63, Luke 2nd Rd., Luzhu Dist
Kaohsiung, 82151
TAIWAN

Re: K151588
Trade/Device Name: maxFiT II Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: March 16, 2016
Received: March 25, 2016

Dear Huang Ching-Chieh:

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,

Erin I. Keith, M.S.
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): K151588

Device Name: maxFiT II Dental Implant System

Indications for Use:

maxFiT II Dental Implant System is for single-stage or two-stage surgical procedures and cemented or screw retained restorations. maxFiT II Dental Implant System is intended for immediate placement and 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. Multiple tooth applications may be splinted with a bar.

Prescription Use ___X___ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

5.1 Type of Submission: Traditional

5.2 Date of Summary: 04/19/2016

5.3 Submitter:

Taiwan Implant Technology Company, Ltd.
Kaohsiung Science Park Branch

Address: 5F., No.63, Luke 2nd Rd., Luzhu Dist.,
Kaohsiung City 82151, Taiwan

Phone: +886-7-695-5561

Fax: +886-7-695-5528

Contact: Ching-Chieh, Huang
(xjay@titc-dental.com)

Registration number: —

5.4 Identification of the Device:

Proprietary/Trade name:	maxFiT II Dental Implant System
Classification Name:	Endosseous Dental Implant
Review Panel:	Dental
Regulation Number:	872.3640
Primary Product Code:	DZE
Secondary Product Code	NHA
Device Classification:	II

5.5 Identification of the Predicate Device:

Predicate Device Name:	ANKYLOS® C/X Dental Implant System
Manufacturer:	DENTSPLY International
Regulation Number:	872.3640
Product Code:	DZE
Device Classification:	II
510(k) Number:	K083805

5.6 Intended Use and Indications for Use of the subject device.

maxFiT II Dental Implant System is for single-stage or two-stage surgical procedures and cemented or screw retained restorations. maxFiT II Dental Implant System is intended for immediate placement and 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. Multiple tooth applications may be splinted with a bar.

5.7 Device Description

The maxFiT II Dental Implant System includes implant, screw and abutment. The maxFiT II Dental Implant System is designed for single-stage or two-stage surgical procedures and cemented or screw retained restorations.

- **Implant**

The maxFiT II Dental Implant System consists of solid threaded, self-tapping dental implants in Ø3.5, 4.2, 5.0, 5.6mm diameters with 8, 10, 12, 14mm lengths. The implant of maxFiT II Dental Implant System is made from CP titanium Grade 4 which complies with ISO 5832-2 and ASTM F67. The implant surface treatment is SLA (Sand-blasted, Large grit, Acid -etched) technology which involves sandblasting with large grit and acid etching techniques, creates micron and macrosubmicron pores morphology.

- **Abutment Models**

The abutments are made of Ti6Al4V Eli, which complies with ISO 5832-3 and ASTM F136.

Item	Description	Specification
Healing Abutment	To protect the inner configuration of the implant, and help the soft tissue of gum naturally formed during the healing process.	D: 4.0mm、4.5mm、5.0mm、5.5mm AH: 1.0mm、3.0mm GH: 1.0mm、2.0mm、3.0mm、4.0mm、5.0mm

Temporary Abutment	To manufacture temporary prostheses. For the temporary crowns and bridges. The abutment height can be modified for clinical cases. The allowable abutment height range is between 4.5 ~ 17mm. And its diameter, wall thickness and angulation cannot be modified.	D: 4.0mm、5.0mm AH: 17mm GH: 1.0mm
Ball Abutment	Used for implant retained mucosa-supported restorations, such as overdentures for fully edentulous patients.	D: 4.0mm GH: 2.0mm、4.0mm
Angled Abutment / Non-hex Angled Abutment	Intended for use in partially or fully edentulous mandibles and maxillae, to support for single or multiple-unit cement retained restorations. It is used when the prosthetic angulation of implant correction is required for bite direction.	D: 4.0mm、4.5mm AH: 7.0mm GH: 2.0mm、4.0mm Angle: 15°、25° Type: A、B (For Angled abutment)
Transfer Abutment / Non-hex Transfer Abutment	Used as an aid in prosthetic restoration, such as cement-retained crowns and bridges.	D: 4.0mm、4.5mm、5.0mm、5.5mm AH: 4.0mm、5.5mm GH: 1.0mm、2.0mm、3.0mm、4.0mm、5.0mm、6.0mm、7.0mm
Locator Abutment	Appropriate for use with overdentures or partial dentures retained in whole or in part by endosseous implants in the mandible or maxilla.	D: 3.5mm H: 1.0mm、2.0mm、3.0mm、4.0mm、5.0mm、6.0mm

- **Abutment connection platforms**

Hex	The hex abutment is the external hexagonal design for preventing implant/abutment rotation. The hexagonal cone could ensure optimum stability.
Non-hex	The non-hex abutment is no anti-rotation, but it still be positioned as desired. The abutment and implant are completely friction-locked by the cone in order to prevent rotation.

5.8 Non-clinical Testing

A series of tests were performed on the proposed device, maxFiT II Dental Implant System.

- Sterilization Test
- Shelf Life Test
- Biocompatibility Test
  - ✧ *In vitro* Cytotoxicity Study
  - ✧ Intracutaneous Reactivity Study
  - ✧ Skin Sensitization Study
  - ✧ Acute Systemic Toxicity (Systemic Injection) Study
  - ✧ Pyrogenicity Study
  - ✧ *In vitro* Bacterial Reverse Mutation (AMES) Study
  - ✧ *In vitro* Chromosome Aberration Study
  - ✧ *In vitro* Mammalian Cell Gene Mutation Study
  - ✧ 14-Day Repeated Exposure Systemic Toxicity Study
  - ✧ 90-Day Bone Implantation Study
- Performance Test
  - ✧ Corrosion test
  - ✧ Fatigue test

Corrosion test has been conducted on SLA-surface treated CP4 dental implant and Ti-6Al-4V abutment. The study is complied with ASTM F746, ASTM F2129 and "Guidance for Industry and Staff – Class II Special Controls Guidance Document:

Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments". The results could prove the maxFiT II Dental Implant System is corrosion resistance.

Fatigue evaluation was performed for demonstrating substantial equivalence under worst case scenario in accordance with ISO 14801 and "Guidance for Industry and Staff – Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments".

All the test results demonstrate that maxFiT II Dental Implant System meets the requirements of its pre-defined acceptance criteria, and is substantially equivalent to the predicate device.

5.9 Clinical Testing

No clinical test data was used to support the decision of substantial equivalence.

5.10 Substantial Equivalence Determination

The maxFiT II Dental Implant System submitted in this 510(k) file is substantially equivalent in intended use, technology/principles of operation, materials and performance to the cleared ANKYLOS® C/X Dental Implant System. Differences between the devices cited in this section do not raise any new issues of substantial equivalence.

	maxFiT II Dental Implant System	**ANKYLOS® C/X Dental Implant System**
510(k) Number	–	K083805
Primary Product Code	DZE	DZE
Secondary Product Code	NHA	–
Intended use	maxFiT II Dental Implant System is for single-stage or two-stage surgical procedures and cemented or screw retained restorations. maxFiT II Dental Implant System is intended for immediate placement and 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. Multiple tooth applications may be splinted with a bar.	The ANKYLOS® C/X Dental Implant System is for single-stage or two-stage surgical procedures and cemented or screw retained restorations. The ANKYLOS® C/X Dental Implant System is intended for immediate placement and 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. Multiple tooth applications may be splinted with a bar.
Surgery Type	One or two stage surgery	One or two stage surgery

Implant		
Drawing		
Design	Thread	Thread

Material	Pure Titanium Grade 4 (ASTM F67、DIN ENISO5832-2)	Pure Titanium Grade 2 (DIN ENISO5832-2)
Body Diameter (D)	Ø3.5mm - Ø5.6mm	Ø3.5mm - Ø7.0mm
Length (L)	8mm - 14mm	8mm - 14mm
Surface treatment	Sandblasted and acid-etched (SLA)	FRIADENT Surface. (Sandblasted and acid-etched)
Implant-Abutment Connection	Tapered	Tapered
Sterilization	Sterile - Gamma Irradiation	Sterile - Gamma Irradiation

Screw		
	Cover Screw	**Spare part ANKYLOS C/X cover screw**
Design	The cover screw locked into the implant	The cover screw locked into the implant
Material	Titanium alloy (Ti-6A1-4V ELI, meets ASTM F-136)	Titanium alloy (Ti-6A1-4V ELI)
Specification	Ø1.8mm	Ø1.0mm
Sterilization	Sterile _ Gamma Irradiation Non-sterile _ Steam Sterilization by user	Non-sterile _ Steam Sterilization by user
	Screw	**ANKYLOS Fixation Screw**
Design	To connect abutment to fixture	To connect abutment to fixture
Material	Titanium alloy (Ti-6A1-4V ELI, meets ASTM F-136)	Titanium alloy (Ti-6A1-4V ELI)
Specification	Ø1.8mm	Ø1.4mm、Ø1.6mm
Sterilization	Sterile _ Gamma Irradiation Non-sterile _ Steam Sterilization by user	Non-sterile _ Steam Sterilization by user

<table>
<tr><td colspan="5">Abutment</td></tr>
<tr><td rowspan="3">Abutments
Connection part with fixture</td><td colspan="2">1.Internal connection
2. Have “Hex” & “Non-hex” two size of connection</td><td colspan="2">1.Internal connection
2.Have “C/” & “/X” two size of connection (non-indexed & indexed prosthetics)</td></tr>
<tr><td>Hex</td><td>The hex abutment is the external hexagonal design for preventing implant/abutment rotation.</td><td>/X</td><td>Are indexed. The index is used to position the abutments in the implants in one of six possible positions.</td></tr>
<tr><td>Non-hex</td><td>The non-hex abutment is no anti-rotation, but it still be positioned as desired. The abutment and implant are completely friction-locked by the cone in order to prevent rotation.</td><td>C/</td><td>Only use the cone for the connection and are not indexed. The abutment components can be positioned as desired and are completely friction-locked by the cone in order to prevent rotation.</td></tr>
<tr><td></td><td colspan="2">Healing abutment</td><td colspan="2">Sulcus Former / Gingiva Former</td></tr>
<tr><td>Design</td><td colspan="2">To protect the inner configuration of the implant, and help the soft tissue of gum naturally formed</td><td colspan="2">To protect the inner configuration of the implant, and help the soft tissue of gum naturally formed</td></tr>
<tr><td>Material</td><td colspan="2">Titanium alloy (Ti-6A1-4V ELI, meets ASTM F-136)</td><td colspan="2">Titanium alloy (Ti-6A1-4V ELI)</td></tr>
<tr><td>Specification</td><td colspan="2">D: 4.0mm、4.5mm、5.0mm、5.5mm
AH: 1.0mm、3.0mm
GH: 1.0mm、2.0mm、3.0mm、4.0mm、5.0mm</td><td colspan="2">(1)ANKYLOS Gingiva Former C
D: 4.2mm
GH: 0.75mm、1.5mm、3.0mm、4.5mm
(2) ANKYLOS Standard C/ Sulcus Former
D: 3.3mm、4.5mm
AH: 4.0mm、6.0mm</td></tr>
</table>

		GH: 1.0mm、3.0mm、4.5mm、6.0mm
Sterilization	Sterile _ Gamma Irradiation Non-sterile _ Steam Sterilization by user	Non-sterile _ Steam Sterilization by user
	Temporary abutment	**Temporary abutment**
Design	To manufacture temporary prostheses For the temporary crowns and bridges	To manufacture temporary prostheses For the temporary crowns and bridges
Material	Titanium alloy (Ti-6A1-4V ELI, meets ASTM F-136)	Titanium alloy (Ti-6A1-4V ELI, meets ASTM F-136)
Specification	D: 4.0mm、5.0mm AH: 17mm GH: 1.0mm	D: 5.5mm、7.0mm AH: 6.0mm、7.5mm GH: 1.5mm、3.0mm Angle: 0°、15°
Sterilization	Sterile _ Gamma Irradiation Non-sterile _ Steam Sterilization by user	zirconia-reinforced PEEK
	Ball abutment	**ANKYLOS® Snap Attachment C/**
Design	Implant retained mucosa-supported restorations	Implant retained mucosa-supported restorations
Material	Titanium alloy (Ti-6A1-4V ELI, meets ASTM F-136)	Titanium alloy (Ti-6A1-4V ELI)
Specification	D: 4.0mm GH: 2.0mm、4.0mm	D: 2.7mm GH: 1.5mm、3.0mm、4.5mm
Sterilization	Sterile _ Gamma Irradiation Non-sterile _ Steam Sterilization by user	Non-sterile _ Steam Sterilization by user
	Angled abutment、Non-hex Angled abutment	**ANKYLOS Regular /X Abutment、ANKYLOS Regular C/ Abutment**
Design	To support for single or multiple-unit cement retained restorations	To support for single or multiple-unit cement retained restorations
Material	Titanium alloy (Ti-6A1-4V ELI, meets ASTM F-136)	Titanium alloy (Ti-6A1-4V ELI)
Specification	D: 4.0mm、4.5mm AH: 7.0mm	D: 5.7mm Head height: 6.6mm、7.0mm、7.4mm、

	GH: 2.0mm、4.0mm Angle: 15°、25° Type: A、B (For Angled abutment)	7.7mm、8.0mm GH: 0.75mm、1.5mm、3.0mm、4.5mm Angle: 7.5°、15°、22.5°、30°、37.5°
Sterilization	Sterile _ Gamma Irradiation Non-sterile _ Steam Sterilization by user	Non-sterile _ Steam Sterilization by user
	Transfer abutment、Non-hex Transfer abutment	**ANKYLOS Regular /X Abutment 、 ANKYLOS Regular C/ Abutment**
Design	Aid in prosthetic restoration	Aid in prosthetic restoration
Material	Titanium alloy (Ti-6A1-4V ELI, meets ASTM F-136)	Titanium alloy (Ti-6A1-4V ELI)
Specification	D: 4.0mm、4.5mm、5.0mm、5.5mm AH: 4.0mm、5.5mm GH: 1.0mm、2.0mm、3.0mm、4.0mm、5.0mm、6.0mm、7.0mm	D: 5.7mm Head height: 6.6mm GH: 0.75mm、1.5mm、3.0mm、4.5mm
Sterilization	Sterile _ Gamma Irradiation Non-sterile _ Steam Sterilization by user	Non-sterile _ Steam Sterilization by user
	Locator abutment	**ANKYLOS LOCATOR Abutment C**
Design	Use with overdentures or partial dentures retained restoration	Use with overdentures or partial dentures retained restoration
Material	Titanium alloy (Ti-6A1-4V ELI, meets ASTM F-136)	Titanium alloy (Ti-6A1-4V ELI)
Specification	D: 3.5mm H: 1.0mm、2.0mm、3.0mm、4.0mm、5.0mm、6.0mm	D: 3.8mm GH: 2.0mm、3.0mm、4.0mm、5.0mm、6.0mm
Sterilization	Sterile _ Gamma Irradiation Non-sterile _ Steam Sterilization by user	Non-sterile _ Steam Sterilization by user

5.11 Similarity and differences

The differences between the proposed device and predicate device are the Grade of Titanium and the design of abutments connection part. The proposed device has tested on safety and performance tests and the results were complied with the test requests. Therefore, the differences of proposed device and predicate device did not raise any problems of substantial equivalence. The proposed device is substantially equivalent to the predicate device in intended use, main materials, safety and performance claims.

5.12 Conclusion

After analyzing bench tests, device description and intended use/indications for use, it can be concluded that maxFiT II Dental Implant System is substantially equivalent to the predicate device.