DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 22, 2016

T-Plus Implant Tech. Co., Ltd.
Dana Cheng
Quality Assurance
No. 41, Wuquan 6th Rd., Wugu Dist.,
New Taipei City, 24889
TAIWAN

Re: K152787
Trade/Device Name: ST Internal Fixture System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: June 17, 2016
Received: June 21, 2016

Dear Dana Cheng:

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,

for 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): K152787

Device Name: ST Internal Fixture System

Indications for Use:

The ST Internal Fixture System is intended to be placed in the upper or lower jaw to support prosthetic devices, such as artificial teeth, and to restore a patient's chewing function. This may be accomplished using either a two stage surgical procedure or a single stage surgical procedure.

The ST Internal Fixture System is intended for use for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

5.1 Type of Submission: Traditional

5.2 Preparation Date: 06/17/2016

5.3 Submitter:

Address: T-Plus Implant Tech. Co., Ltd.
No.41, Wuquan 6th Rd., Wugu Dist., New Taipei City 24889, Taiwan (R.O.C)
Phone: 886-2-22981950
Fax: 886-2-22984353
Contact: Dana Cheng (tplus.dana@gmail.com)

5.4 Identification of the Device:

Proprietary/Trade name:	ST Internal Fixture System
Classification Name:	Endosseous dental implant
Device Classification:	II
Panel:	Dental
Regulation Number:	872.3640
Primary Product code:	DZE
Subsequent Product code:	NHA

5.5 Primary Predicate Device (K132992):

Predicate Device Name:	Ti Star Implant System T-Plus Implant Tech. Co., Ltd.
Device Classification:	II
Review Panel:	Dental
Regulation Number:	872.3640
Primary Product code:	DZE
Subsequent Product code:	NHA

5.6 Reference Predicate Device (K052369):

Predicate Device Name:	ExFeel Dental Implant System
Manufacturer:	MegaGen Co., Ltd.
Device Classification:	II
Review Panel:	Dental
Regulation Number:	872.3640
Product Code:	DZE

5.7 Intended Use and Indications for Use of the subject device

The ST Internal Fixture System is intended to be placed in the upper or lower jaw to support prosthetic devices, such as artificial teeth, and to restore a patient's chewing function. This may be accomplished using either a two stage surgical procedure or a single stage surgical procedure.

The ST Internal Fixture System is intended for use for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

5.8 Device Description

The ST Internal Fixtures are made with Grade 4 titanium. The systems consist of one-stage and two-stage root form dental implants, associated with abutment systems, which provide the dentist with screw and cement retained restoration options.

The devices covered by this submission are ST internal fixture, screw and abutment. The diameters of ST internal fixtures are 3.5 mm, 4.0 mm, 4.5 mm, and 5.0 mm, and the lengths are 7.0 mm, 8.5 mm, 10.0 mm, 11.5 mm, 13.0 mm, and 15.0 mm.

The range of diameters and angulations for each screw model and abutment model are provided as below:

Component	Specification (mm)				Angulation range
	D	L	cuff	Post H	
ST Cover Screw	3.15, 3.35, 3.7, 3.9	N/A	N/A	0.4, 2.0	N/A
ST Healing screw	4.0, 4.5, 5.0, 6.0, 7.0	N/A	N/A	3.0, 4.0, 5.0, 6.0, 7.0	N/A
ST Abutment screw	2.3, 2.5	10.8, 8.6	N/A	N/A	N/A
ST EZ Post Abutment	4.5, 5.0, 6.0, 7.0	N/A	1.0, 2.0, 3.0, 4.0, 5.0	4.0, 5.5, 7.0,	N/A
ST Solid Abutment	4.0, 4.5, 5.0, 6.0, 7.0	N/A	1.0, 2.0, 3.0, 4.0, 5.0	4.0, 5.5, 7.0	N/A
ST Angled Abutment	4.0, 5.0, 6.0	N/A	1.0, 2.0, 3.0, 4.0, 5.0	N/A	15°, 25°

5.9 Non-clinical Testing

A series of tests were performed to assess the proposed device is substantially equivalent to the predicate devices. All the test results demonstrate that ST Internal Fixture System meets the requirements of its pre-defined acceptance criteria and intended use.

- Sterilization Test (leveraged from own K132992 predicate)
- Shelf Life Test (leveraged from own K052369 predicate)
- Biocompatibility testing (leveraged from own K052369 predicate):
  - Cytotoxicity Test
  - Intracutaneous Reactivity Test
  - Maximization Sensitization Test
  - Systemic Injection Test (Intravenous Injection)
  - Pyrogen Test
  - 90-Day Bone Implantation Study

- Performance testing:
  - Fatigue test

A fatigue test is required to evaluate the stability of implant system in oral cavity. The fatigue testing has been conducted on the proposed device in accordance with ISO 14801. Test results comply with ISO14801. It approves the proposed device is substantially equivalent to the predicate devices.

- RBM surface coating

ST Internal Fixtures and the predicate devices undergo an implant surface treatment of Resorbable Blast Media (RBM). The cleaning validation test and SEM/EDX analysis have been conducted on the proposed device to verify that any particles or chemicals used to remove particles have been washed from the surface.

5.10 Clinical Testing

No additional clinical testing was necessary for a determination of substantial equivalence. The results of non-clinical testing indicated the device was found to be substantially equivalent to the predicate devices.

5.11 Substantial Equivalence Determination

The ST Internal Fixture System submitted in this 510(k) file is substantially equivalent in main materials, implant surface treatment, angulation range, safety and performance claims to the cleared Ti Star Implant System (K132992) and ExFeel Dental Implant system (K052369). Differences of proposed device and predicate devices do not raise new issues of substantial equivalence.

	Proposed device	Predicate device	
Item	ST Internal Fixture system	Ti Star Implant System	ExFeel Dental Implant System
Manufacturer	T-Plus Implant Tech. Co., Ltd.	T-Plus Implant Tech. Co., Ltd.	MegaGen Co., Ltd.
510(k) Number	K152787	K132992	K052369
Classification	Class II	Class II	Class II
Indication for Use	The ST Internal Fixture System is intended to be placed in the upper or lower jaw to support prosthetic devices, such as artificial teeth, and to restore a patient's chewing function. This may be accomplished using either a two stage surgical procedure or a single stage surgical procedure. The ST Internal Fixture System is intended for use for immediate loading when good primary stability is achieved and with appropriate occlusal loading.	The Ti Star Implant System is intended to be placed in the upper or lower jaw to support prosthetic devices, such as artificial teeth, and to restore a patient's chewing function. This may be accomplished using either a two stage surgical procedure or a single stage surgical procedure. The Ti Star Implant System is intended for use for immediate loading when good primary stability is achieved and with appropriate occlusal loading.	The ExFeel Dental Implant Systems are intended to be placed in the upper or lower jaw to support prosthetic devices, such as artificial teeth, and to restore a patient's chewing function. This may be accomplished using either a two stage surgical procedure or a single stage surgical procedure.

Implant

		Proposed device	Predicate device	
Item		ST Internal Fixture system	Ti Star Implant System	ExFeel Dental Implant System
Material		C.P Titanium and Titanium Alloy	C.P Titanium and Titanium Alloy	C.P Titanium and Titanium Alloy
Implant surface treatment		RBM	RBM	RBM
Implant to abutment connection		Internal Hex Connection	Internal Octa Connection	Internal and External Hex
Implant Sterile		Yes	Yes	Yes
Sterilization		Gamma Irradiation	Gamma Irradiation	Gamma Irradiation
Implant size (mm)	Diameters	3.5, 4.0, 4.5, 5.0	3.5, 4.1, 4.8	3.75 – 5.5
	Lengths	7.0, 8.5, 10.0, 11.5, 13.0, 15.0	7.0, 8.5, 10.0, 11.5, 13.0, 15.0	7.0 – 18.0

Abutment model

	Proposed device	Predicate device	
Item	ST Internal Fixture system	Ti Star Implant System	ExFeel Dental Implant System
Material	C.P Titanium and Titanium Alloy	C.P Titanium and Titanium Alloy	C.P Titanium and Titanium Alloy
EZ Post Abutment			
Diameters (mm)	4.5, 5.0, 6.0, 7.0	5.5	4.0, 5.0, 6.0
Cuff	1.0, 2.0, 3.0, 4.0, 5.0	1.5, 2.5, 3.5, 4.5	-
Post H	4.0, 5.5, 7.0	5.5	-
Solid Abutment			
Diameters (mm)	4.0, 4.5, 5.0, 6.0, 7.0	3.5	-
Cuff H	1.0, 2.0, 3.0, 4.0, 5.0	-	-
Post H	4.0, 5.5, 7.0	4.0, 5.5, 7.0	-

Angled Abutment Diameters (mm) Cuff Angulation range	 4.0, 5.0, 6.0 1.0, 2.0, 3.0, 4.0, 5.0 15°、25°	 - - -	 4.0, 5.0, 6.0 2.0, 4.0 15°、25°
Sterilization	None	None	None

5.12 Similarity and differences

The differences between the proposed device and the predicate devices are the design of implant to abutment connection and accessory components. The proposed device was tested, and the results complied with the pre-defined success criteria. Therefore, the differences of proposed device and predicate devices did not raise any problems of substantial equivalence. The proposed device is substantially equivalent to the predicate devices in intended use, design, safety and performance claims.

5.13 Conclusion

After analyzing bench tests, device description and intended use/indications for use, it can be concluded that ST Internal Fixture System is substantially equivalent to the predicate devices.