February 27, 2020

T-Plus Implant Tech. Co., Ltd.
℅ Yuhua Chen
Official Correspondent
PuHsu Consulting Ltd.
7F., No.272, Jiankang Rd., Zhonghe Dist.
New Taipei County 23553
TAIWAN

Re: K190919
Trade/Device Name: ST Internal Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: January 20, 2020
Received: January 28, 2020

Dear Yuhua Chen:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Srinivas Nandkumar, Ph.D.
Director
DHT1B: Division of Dental Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT, and Dental Devices
Office of Product Evaluation and Quality
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)*
K190919

Device Name
ST Internal Implant System

Indications for Use *(Describe)*
The ST Internal 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 ST Internal Implant System is intended for use for immediate loading when good primary stability is achieved and with appropriate occlusal 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Date prepared: February 27, 2020

1 Submission Submitter

Company Name	T-Plus Implant Tech. Co., Ltd.
Address	No.41, Wuquan 6th Rd., Wugu Dist., New Taipei County 24889, Taiwan
Contact	Dana Cheng
Phone	886-2-22981950
Fax	886-2-22984353
Email	danacheng@tplus.com.tw

2 Submission Correspondent

Company Name	PuHsu Consulting Ltd.
Address	7F., No.272, Jiankang Rd., Zhonghe Dist., New Taipei County 23553, Taiwan
Contact	Yuhua Chen
Cell Phone	886-965650265
Email	yuhua@puhsuconsult.com

3 Device Name

Proprietary/Trade Name	ST Internal Implant System
Classification Name	Endosseous dental implant
Device Classification	II
Panel	Dental
Regulation Number	21 CFR 872.3640
Primary Product Code	DZE
Secondary Product Code	NHA

4 Predicate Device

Primary Predicate	K152787, ST Internal Fixture System
Reference Devices	K152786, A Plus Internal Fixture System
	K132992, Ti Star Implant System
	K122231, Xpeed AnyRidge Internal Implant System
	K123988, AnyOne™ Internal Implant System
	K083496, CAMLOG Abutments
	K182313, BoneTrust® Implant System

5 Device Description

The ST Internal Implant System are made with Grade 4 titanium and surface treatment is done with SLA (Sand-blasted, Large grit, Acid-etched). 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 system are ST internal implant, screw and abutment. The implants in this system are provided in lengths from 7.0-15.0 and in diameters from 3.7-5.1. The 3.7 diameter implant is not provided in the 7.0 length.

The ST implants have two types, one is mini and the other is regular. The mini type diameters of ST implants are 3.7 mm and the lengths are 8.5 mm, 10.0 mm, 11.5 mm, 13.0 mm, and 15.0 mm. The regular type diameters of ST implants are 4.2 mm, 4.6 mm, and 5.1 mm, and the lengths are 7.0 mm, 8.5 mm, 10.0 mm, 11.5 mm, 13.0 mm, and 15.0 mm. EZ Post abutments, solid abutments, Cylinder abutments, angled abutments, mount screws, cover screws, abutment screws and fixture mounts are included in the system.

The characteristics of ST Internal Implant and Abutments are provided as below:

Implant		
Specification		**Description**
Mini type	Diameter (mm)	3.7
	Length (mm)	8.5, 10.0, 11.5, 13.0, 15.0
Regular	Diameter (mm)	4.2, 4.6, 5.1

Implant		
type	Length (mm)	7.0, 8.5, 10.0, 11.5, 13.0, 15.0
Design		Threaded, screw type, root-form, fixation, tapered, internal and morse taper, internal hexagonal connection
Material		CP Titanium Gr.4
Surface Treatment		SLA
Sterilization		Sterile. Sterilized by Gamma irradiation.

Abutments		
Item	**Specification**	**Description**
EZ Post abutments	Diameter (mm)	4.6, 5.0 (for Mini type) 4.6, 5.0, 6.0, 7.0 (for Regular type)
	Cuff Height (mm)	0.8, 1.8, 2.8, 3.8, 4.8
	Lengths (mm)	8.5 – 14.6 (for Mini type) 8.5 – 14.5 (for Regular type)
	Design	Hexagonal connection
	Material	CP Titanium Gr.4
	Surface Treatment	Anodized
	Sterilization	Non-sterile. Moist heat sterilization must be conducted by the user before use.
Solid abutments	Diameter (mm)	4.0, 4.6 (for Mini type) 4.0, 4.6, 5.0, 6.0, 7.0 (for Regular type)
	Cuff Height (mm)	0.8, 1.8, 2.8, 3.8, 4.8
	Lengths (mm)	10 – 17.0 (for Mini type) 10.4 – 15.9 (for Regular type)
	Design	Circular connection
	Material	Titanium Gr.5
	Surface Treatment	Anodized
	Sterilization	Non-sterile. Moist heat sterilization must be conducted by the user before use.
Cylinder abutments	Diameter (mm)	4.0, 5.0 (for Mini type) 4.0, 5.0, 6.0 (for Regular type)
	Lengths (mm)	10.6 – 14.6 (for Mini type) 10.5 – 14.5 (for Regular type)
	Design	Hexagonal connection
	Material	CP Titanium Gr.4

Abutments		
Item	**Specification**	**Description**
	Surface Treatment	Anodized
	Sterilization	Non-sterile. Moist heat sterilization must be conducted by the user before use.
	Angulation range	0°
Angled abutments	Diameter (mm)	4.6, 5.0, 6.0
	Cuff Height (mm)	1.0, 2.0, 3.0, 4.0
	Angulation range	15°, 25°
	Design	Hexagonal connection
	Material	CP Titanium Gr.4
	Surface Treatment	Anodized
	Sterilization	Non-sterile. Moist heat sterilization must be conducted by the user before use.

6 Indications for Use

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

7 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 Implant 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 K132992 and K152787 predicate)
- Biocompatibility testing
  - 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.
  - SLA surface treatment

    ST Internal Implant System undergoes an implant surface treatment of Sand-blasted, Large grit, Acid-etched (SLA) which differs from the predicate devices. The cleaning validation tests 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. The SEM/EDX analysis verifies that there were no elements besides titanium found on the surface of the implant.

8 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.

9 Substantial Equivalence Determination

The ST Internal Implant System submitted in this 510(k) file is substantially equivalent in the design of implant to abutment connection, main materials, angulation range, safety and performance claims to the cleared ST Internal Fixture System (K152787), A Plus Internal Fixture System (K152786), Ti Star Implant System (K132992), Xpeed AnyRidge Internal Implant System (K122231), AnyOne™ Internal Implant System (K123988), CAMLOG Abutments (K083496), and BoneTrust® Implant System (K182313). Differences between the proposed device system and the predicate device have been resolved through biocompatibility and performance testing which shows substantial equivalence of the subject device.

9.1 Implant, Cylinder Abutment, Angled Abutment

Feature		Proposed device	Primary Predicate -1 T-Plus Implant Tech. Co., Ltd.	Reference Device -2 T-Plus Implant Tech. Co., Ltd.	Reference Device -3 T-Plus Implant Tech. Co., Ltd.	Reference Device -4 MegaGen Implant Co., Ltd.	Reference Device -5 MegaGen Implant Co., Ltd.	**Comments**
		ST Internal Implant System	ST Internal Fixture System (K152787)	A Plus Internal Fixture System (K152786)	Ti Star Implant System (K132992)	$AnyOne^{TM}$ Internal Implant System (K123988)	Xpeed AnyRidge Internal Implant System (K122231)	
Indication for Use		The ST Internal 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 ST Internal Implant System is intended for use for immediate loading when good primary stability is achieved and with appropriate occlusal loading.	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 A Plus 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. It is intended for delayed 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 $AnyOne^{TM}$ Internal Implant System is intended to be surgically places in the maxillary or mandibular molar areas for the purpose providing prosthetic support for dental restoration (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function. Smaller implant (less than Ø6.0mm) are dedicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region and are indicated for delayed loading.	The Xpeed AnyRidge Internal Implant System is intended to be surgically places in the maxillary or mandibular molar areas for the purpose providing prosthetic support for dental restoration (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function. Smaller implant (less than Ø6.0mm) are dedicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region and are indicated for delayed loading.	Identical to predicate device 1, 2, 3
Material		C.P Titanium	C.P Titanium	C.P Titanium and Titanium Alloy	C.P Titanium and Titanium Alloy	CP4 Titanium and Ti-6Al-4V-ELI	CP Titanium, Gr.4 and Ti-6Al-4V-ELI	Identical to predicate device 1
Implant surface treatment		SLA	RBM	RBM	RBM	SLA	SLA	Equivalent to predicate device 4, 5
Implant to abutment connection		Internal Hex Connection	Internal Hex Connection	Internal Hex Connection	Internal Hex Connection	Internal Hex	Internal Hex	Identical
Implant Sterile		Yes	Yes	Yes	Yes	Yes	Yes	Identical
Sterilization		Gamma	Gamma	Gamma	Gamma	Gamma	Gamma	Identical
Implant size	Diameter (mm) and Length (mm)	Ø 3.7 mm: 8.5, 10.0, 11.5, 13.0, 15.0 mm Ø 4.2 mm: 7.0, 8.5, 10.0, 11.5, 13.0, 15.0 mm Ø 4.6 mm: 7.0, 8.5, 10.0, 11.5, 13.0, 15.0 mm Ø 5.1 mm: 7.0, 8.5, 10.0, 11.5, 13.0, 15.0 mm	Ø 3.5 mm: 8.5, 10.0, 11.5, 13.0, 15.0 mm Ø 4.0 mm: 7.0, 8.5, 10.0, 11.5, 13.0, 15.0 mm Ø 4.5 mm: 7.0, 8.5, 10.0, 11.5, 13.0, 15.0 mm Ø 5.0 mm: 7.0, 8.5, 10.0, 11.5, 13.0, 15.0 mm	Ø 3.4 mm: 8.0, 10.0, 12.0, 14.0 mm Ø 3.8 mm: 8.0, 10.0, 12.0, 14.0 mm Ø 4.3 mm: 8.0, 10.0, 12.0, 14.0 mm Ø 4.8 mm: 8.0, 10.0, 12.0, 14.0 mm Ø 5.3 mm: 8.0, 10.0, 12.0, 14.0 mm	Ø 3.5 mm: 7.0, 8.5, 10.0, 11.5, 13.0, 15.0 mm Ø 4.1 mm: 7.0, 8.5, 10.0, 11.5, 13.0, 15.0 mm Ø 4.8 mm: 7.0, 8.5, 10.0, 11.5, 13.0, 15.0 mm	Normal Thread Ø 3.9 mm: 7.0, 8.5, 9.5, 11.0, 12.5, 14.5 mm Ø 4.3mm: 7.0, 8.5, 9.5, 11.0, 12.5, 14.5 mm Ø 4.8 mm: 7.0, 8.5, 9.5, 11.0, 12.5, 14.5 mm Ø 5.3 mm: 7.0, 8.5, 9.5, 11.0, 12.5, 14.5 mm Ø 6.3 mm: 7.0, 8.5, 9.5, 11.0, 12.5, 14.5 mm	Normal Ridge Ø 4.0 mm: 7.7, 9.2, 10.7, 12.2, 14.2, 17.2 mm Ø 4.4 mm: 7.7, 9.2, 10.7, 12.2, 14.2, 17.2 mm Ø 4.9 mm: 7.7, 9.2, 10.7, 12.2, 14.2, 17.2 mm Ø 5.4 mm: 7.7, 9.2, 10.7, 12.2, 14.2, 17.2 mm Ø 5.9 mm: 7.7, 9.2, 10.7, 12.2, 14.2, 17.2 mm	Diameters and lengths are within the range of predicate device 1 and 2. However, the Ø 5.1x7.0mm is within range of predicate device 4 and the Ø 5.1x15.0mm is within range of predicate device 5.

Feature		Proposed device	Primary Predicate -1 T-Plus Implant Tech. Co., Ltd.	Reference Device -2 T-Plus Implant Tech. Co., Ltd.	Reference Device -3 T-Plus Implant Tech. Co., Ltd.	Reference Device -4 MegaGen Implant Co., Ltd.	Reference Device -5 MegaGen Implant Co., Ltd.	**Comments**
		ST Internal Implant System	ST Internal Fixture System (K152787)	A Plus Internal Fixture System (K152786)	Ti Star Implant System (K132992)	$AnyOne^{TM}$ Internal Implant System (K123988)	Xpeed AnyRidge Internal Implant System (K122231)	
						Ø 7.3 mm: 7.0, 8.5, 9.5, 11.0, 12.5, 14.5 mm Deep Thread Ø 4.8 mm: 7.0, 8.5, 9.5, 11.0, 12.5, 14.5 mm Ø 5.8 mm: 7.0, 8.5, 9.5, 11.0, 12.5, 14.5 mm Ø 6.8 mm: 7.0, 8.5, 9.5, 11.0, 12.5, 14.5 mm Ø 7.8 mm: 7.0, 8.5, 9.5, 11.0, 12.5, 14.5 mm Ø 8.3 mm: 7.0, 8.5, 9.5, 11.0, 12.5, 14.5 mm		
Cylinder Abutment size	Diameter (mm)	4.0, 5.0, 6.0	-	-	-	3.8 – 10.0	-	Diameters are within range of predicate device 4
	Length (mm)	10.5 – 14.6	-	-	-	7.7 -18.7	-	Length are within range of predicate device 4
Angled Abutment size	Diameter (mm)	4.6, 5.0, 6.0	4.0, 5.0, 6.0	4.0, 5.0, 6.0	-	3.8 – 10.0	-	Diameters are within range of predicate device 1
	Cuff Height (mm)	1.0, 2.0, 3.0, 4.0	1.0, 2.0, 3.0, 4.0, 5.0	2.0, 3.0, 4.0, 5.0	-	-	-	Cuff heights are within range of predicate device 1
	Angulation range	15°, 25°	15°, 25°	15°, 25°	-	15°, 25°	-	Identical to predicate device 1, 2, 4

9.2 EZ Post Abutment

Feature	Proposed device ST Internal Implant System	Primary Predicate -1 T-Plus Implant Tech. Co., Ltd. ST Internal Fixture System (K152787)	Reference Device -2 Altatec GmbH CAMLOG Abutments (K083496)	Reference Device -3 Medical Instinct Deutschland GmbH BoneTrust® Implant System (K182313)	**Comments**
Material	CP Titanium Gr.4	CP Titanium Gr.4	Titanium alloy TiAl4V	Titanium alloy TiAl4V	Identical to predicate device 1
Surface	Anodized surface	Anodized surface	Anodized surface	Anodized surface	Identical
Diameter (mm)	4.6, 5.0 (for Mini type) 4.6, 5.0, 6.0, 7.0 (for Regular type)	4.0, 5.0, 6.0, 7.0	3.8, 4.3, 5.0, 6.0	3.4, 4.0, 5.0	Diameters are within range of predicate device 1
Cuff Height (mm)	0.8, 1.8, 2.8, 3.8, 4.8	1.0, 2.0, 3.0, 4.0, 5.0	0.8, 1.5	0.5, 0.7, 2.5, 4.5	The minimum length is identical to predicate device 2 and bigger than device 3, and the maximum length is smaller than predicate device 1.
Connection	Hexagonal connection	Hexagonal connection	Conical fitting	Cylindrical external Hexagon or and conical torx	Identical to predicate device 1
Angulation range	0°	0°	0°, 15°, 20°	0°, 15°, 20°	Identical to predicate device 1

9.3 Solid Abutment

Feature	Proposed device	Primary Predicate -1 T-Plus Implant Tech. Co., Ltd.	Reference Device -2 Altatec GmbH	Reference Device -3 Medical Instinct Deutschland GmbH	**Comments**
	ST Internal Implant System	ST Internal Fixture System (K152787)	CAMLOG Abutments (K083496)	BoneTrust® Implant System (K182313)	
Material	Titanium Gr.5	Titanium Gr.5	Titanium alloy TiAl4V	Titanium alloy TiAl4V	Identical to predicate device 1
Surface	Anodized surface	Anodized surface	Anodized surface	Anodized surface	Identical
Diameter (mm)	4.0, 4.6 (for Mini type) 4.0, 4.6, 5.0, 6.0, 7.0 (for Regular type)	4.0, 4.5, 5.0, 6.0, 7.0	3.8, 4.3, 5.0, 6.0	3.4, 4.0, 5.0	Diameters are within range of predicate device 1
Cuff Height (mm)	0.8, 1.8, 2.8, 3.8, 4.8	1.0, 2.0, 3.0, 4.0, 5.0	0.8, 1.5	3.0	The minimum length is identical to predicate device 2, and the maximum length is smaller than predicate device 1.
Connection	Circular connection	Circular connection	Conical fitting	Cylindrical external Hexagon or and conical torx	Identical to predicate device 1
Angulation range	0°	0°	0°, 15°, 20°	0°	Identical to predicate device 1 and 3

10 Similarity and differences

The differences between the proposed device and the predicate devices are accessory components, and implant surface treatment. 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.

11 Conclusion

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