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

September 12, 2016

AGS Medikal Urunleri Ith. Ihr. Tic. Ltd. Sti.
% H. Semih Oktay, Ph.D.
President
CardioMed Device Consultants, LLC
5523 Research Park Drive, Suite 205
Baltimore, Maryland 21228

Re: K160221
Trade/Device Name: Implance Dental Implant System, Implance Dental Abutment System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: August 9, 2016
Received: August 10, 2016

Dear H. Semih Oktay:

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)*
K160221

Device Name
Implance Dental Implant System
Implance Dental Abutment System

Indications for Use *(Describe)*
Implance Dental Implant System is indicated to use for surgical placement in the upper and lower jaw arches, to provide a root form means for single and multiple units' prosthetic appliance attachment to restore a patient's chewing function.

Implance Dental Implant can be placed 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.

Immediate loading is restricted to the anterior mandible based on four splinted-interforminal placed implants.

Implance Dental Abutment System is used with a dental implant to provide support to prosthetic restorations such as crown, bridge and overdentures in partially or fully edentulous patients. Octa Abutment models that contain an abutment post height less than 4 mm are indicated only for multi-unit loading, such as bridge or overdenture.

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

I. SUBMITTER

AGS Medikal Urunleri Ith. Ihr. Tic. Ltd. Sti.
Mehmet Afkan Sok. No: 57 Kat: 1, 34718
Kosuyolu-Kadikoy
Istanbul, TURKEY Phone:
00902165460078
Fax: 00902165460079

US Consultant: Semih
Oktay
5523 Research Park Drive, Suite 205
Baltimore, MD 21228
Phone: (410) 674-2060
Email: soktay@cardiomedllc.com

Date of Summary September 7, 2016

II. DEVICE

Proprietary name	Implance Dental Implant System Implance Dental Abutment System
Common name	Endosseous Dental Implant & Abutments
Classification name	21 CFR 872.3640 Endosseous Dental implant
Regulatory Class	II
Product Codes	DZE (Primary Product Code), NHA

III. PREDICATE DEVICE

Primary Predicate Device:	Dentis Dental Device - K073486
Predicate Device:	Klockner Dental implant abutment - K122988

IV DEVICE DESCRIPTION

The Implance Dental Implant System consists of titanium/titanium alloy dental implants and titanium closing screws. The Implance Dental Implants are intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as an artificial tooth, in order to restore the patient's chewing function. The surface of the implant is sand-blasted with a resorbable blast media (RBM). The provided closing screw covers the Implance Dental Implant during the healing process.

The Implance Dental Implants (Table 1) are either bone level or tissue level type implants and are available in multiple designs. Bone Level Implants primarily contact bone, whereas the Tissue Level implant contacts bone and tissue along the cuff portion of the dental implant.

Table 1 Implance Dental Implant System Specifications

Feature	Bone Level	Tissue Level
Connection	Platform	Platform
	Internal	Internal
	Hexagonal	Octagonal
Diameters (mm)	3.3; 3.7; 4.3; 4.8 ; 5.5	3.7; 4.3; 4.8 ; 5.5
Length (mm)	8, 10, 12, 14	8, 10, 12, 14

The Implance Dental Abutment System (Table 2), consisting of titanium temporary and final abutments and screws, provides the link between the Implance Dental Implant and the prosthesis that forms the superstructure and allows chewing. Final, permanent abutments are available in multiple designs and range in diameter from 2.9 mm to 6.5 mm; cuff heights of 0.5 mm to 5 mm and lengths of 7 mm to 16.4 mm.

Table 2 Implance Dental Abutment Types

GENERAL SPECIALTIES		
Name	**Type**	**Patient specific customization**
COUPLE ABUTMENT	Cement-retained Final-type Screw Required	Yes
ANGLED ABUTMENT BONE LEVEL	Cement-retained Final-type Screw Required	No
SOLID ABUTMENT	Cement-retained Final-type	No
O-RING ABUTMENT	attachment-retained Final-type	No
MULTI ABUTMENT	Cement-retained Final-type Screw Required	Yes
OCTA ABUTMENT	Attachment and Screw-retained Final-type	No
SYNOCTA ABUTMENT TISSUE LEVEL	Cement-retained Final-type Screw Required	Yes
HEALING ABUTMENT	temporary	No

Table 3 Implance Dental Abutment Sizes

	Tissue level / Bone level	Platform Diameter (mm)	Cuff height (mm)	Length (mm)		Implant connection	Raw material
HEALING ABUTMENTS	Bone Level (for Ø 3.3mm implants)	3.70	2.50	7.00		conic internal connection	Ti Gr 5
		3.70	3.50	8.00			
		3.70	5.00	9.50			
		3.70	7.00	11.50			
	Bone level (for Ø 3.7, 4.3, 4.8, 5.5 mm implants)	4.5 - 5.5 -6.5	1.00	9.50		conic internal connection	Ti Gr 5
			2.00	10.50			
			3.00	11.50			
			4.00	12.50			
			5.00	13.50			
	Tissue level(for Ø 3.7, 4.3, 4.8mm implants)	5.20	3.00	7.40		conic internal connection	Ti Gr 4
		5.20	4.00	8.40			
		5.20	5.50	9.90			
	Tissue level (for Ø 5.5mm implants)	6.40	3.00	7.40		conic internal connection	Ti Gr 4
		6.40	4.00	8.40			
		6.40	5.50	9.90			
SOLID ABUTMENTS	Bone Level (for 3.3mm implants)	3.70	1.00	11.50		conic internal connection	Ti Gr 5
		3.70	2.00	12.50			
		3.70	3.00	13.50			
		3.70	4.00	14.50			
		3.70	5.00	15.50			
	Bone Level (for Ø 3.7, 4.3, 4.8, 5.5 mm implants)	4.5 - 5.5 -6.5	1.00	12.40		conic internal connection	Ti Gr 5
			2.00	13.40			
			3.00	14.40			
			4.00	15.40			
			5.00	16.40			
	Tissue level (for Ø 3.7, 4.3, 4.8mm implants)	3.50	--	9.00		conic internal connection	Ti Gr 4
		3.50	--	10.50			
		3.50	--	12.00			
	Tissue level (for Ø 5.5mm implants)	4.30	--	9.00		conic internal connection	Ti Gr 4
		4.30	--	10.50			
		4.30	--	12.00			

COUPLE ABUTMENTS	Bone Level (for Ø 3.3mm implants)	3.70	1.00	8.50		conic hexagonal internal connection (Ø 2.1mm hex)	Ti Gr 5
		3.70	2.00	9.50			
		3.70	3.00	10.50			
		3.70	4.00	11.50			
		3.70	5.00	12.50			
	Bone level (for Ø 3.7, 4.3, 4.8, 5.5 mm implants)	4.5 - 5.5 -6.5	1.00	8.90		conic hexagonal internal connection (Ø 2.495mm hex)	Ti Gr 5
			2.00	9.90			
			3.00	10.90			
			4.00	11.90			
			5.00	12.90			
	Bone level Non Hex (for Ø 3.3mm implants)	3.70	1.00	8.50		conic non-hexagonal internal connection	Ti Gr 5
		3.70	2.00	9.50			
		3.70	3.00	10.50			
		3.70	4.00	11.50			
		3.70	5.00	12.50			
	Bone level Non Hex (for Ø 3.7, 4.3, 4.8, 5.5 mm implants)	4.5 - 5.5 -6.5	1.00	8.70		conic non-hexagonal internal connection	Ti Gr 5
			2.00	9.70			
			3.00	10.70			
			4.00	11.70			
			5.00	12.70			
	Tissue level (for Ø 3.7, 4.3, 4.8mm implants)	5.20	1.00	8.75		conic octagonal internal connection (Ø 3.095mm octa)	Ti Gr 4
		5.20	2.00	9.75			
		5.20	3.00	10.75			
		5.20	4.00	11.75			
	Tissue level (for Ø 5.5mm implants)	6.40	1.00	8.75		conic octagonal internal connection (Ø 3.095mm octa)	Ti Gr 4
		6.40	2.00	9.75			
		6.40	3.00	10.75			
		6.40	4.00	11.75			
	Tissue level non-octa (for Ø 3.7, 4.3, 4.8mm implants)	5.20	1.00	8.75		non-octagonal internal connection	Ti Gr 4
		5.20	2.00	9.75			
		5.20	3.00	10.75			
		5.20	4.00	11.75			
	Tissue level non-octa (for Ø 5.5mm implants)	6.40	1.00	8.75		non-octagonal internal connection	Ti Gr 4
		6.40	2.00	9.75			
		6.40	3.00	10.75			
		6.40	4.00	11.75			

MULTI ABUTMENTS	Bone level (for Ø 3.3mm implants)	3.70	1.00	14.50		conic hexagonal internal connection (Ø 2.1mm hex)	Ti Gr 5
	Bone level (for Ø 3.7, 4.3, 4.8, 5.5 mm implants)	4.50	1.00	15.63		conic hexagonal internal connection (Ø 2.495mm hex)	Ti Gr 5
		5.50	1.00	15.63			
	Bone level- Non hex (for Ø 3.3mm implants)	3.70	1.00	14.50		conic non-hexagonal internal connection	Ti Gr 5
	Bone level- Non hex (for Ø 3.7, 4.3, 4.8, 5.5 mm implants)	4.50	1.00	15.63		conic non-hexagonal internal connection	Ti Gr 5
		5.50	1.00	15.63			
	Tissue level	5.20	--	13.50		conic octagonal internal connection (Ø 3.095mm octa)	Ti Gr 4
	Tissue level-Non octa	5.20	--	13.50		conic non-octagonal internal connection	Ti Gr 4
OCTA ABUTMENTS	Bone level (for Ø 3.3mm implants)	4.80	1.00	8.65		conic hex internal connection (Ø 2.1mm hex)	Ti Gr 5
		4.80	2.00	9.65			
		4.80	3.00	10.65			
		4.80	4.00	11.65			
		4.80	5.00	12.65			
	Bone level (for Ø 3.7, 4.3, 4.8, 5.5 mm implants)	4.80	1.00	9.10		conic hex internal connection (Ø 2.495mm hex)	Ti Gr 5
		4.80	2.00	10.10			
		4.80	3.00	11.10			
		4.80	4.00	12.10			
		4.80	5.00	13.10			
	Tissue level	3.50	--	7.00		conic octa internal connection (Ø 3.095mm octa)	Ti Gr 4
SYNOCTA ABUTMENT	Tissue level	3.50	--	8.80		conic octagonal internal connection (Ø 3.095mm octa)	Ti Gr 4
	Tissue level-Non octa	3.50	--	8.80		conic non-octagonal internal connection	

O-RING ABUTMENTS	Bone level (for Ø 3.3mm implants)	2.90	0.50	9.50		conic internal connection	Ti Gr 5
		3.70	2.00	11.10			
		3.70	4.00	13.10			
	Bone level (for Ø 3.7, 4.3, 4.8, 5.5 mm implants)	3.42	0.50	10.10		conic internal connection	Ti Gr 5
		4.50	2.00	11.60			
		4.50	4.00	13.60			
	Tissue level	3.50	0.50	9.10		conic internal connection	Ti Gr 4
		3.50	2.00	11.10			
		3.50	4.00	13.10			

	Bone level	Platform Diameter (mm)	Cuff height (mm)	Length (mm)	Angle	Implant connection	Raw material
ANGLED ABUTMENTS	Bone level (for Ø 3.3mm implants)	3.70	1.00	8.50	15°	conic hexagonal internal connection (Ø 2.1mm hex)	Ti Gr 5
		3.70	2.00	9.50	15°		
		3.70	4.00	11.50	15°		
	Bone level (for Ø 3.7, 4.3, 4.8, 5.5 mm implants)	4.50	2.00	10.59	15°	conic hexagonal internal connection (Ø 2.495mm hex)	Ti Gr 5
		4.50	2.00	10.95	25°		
		4.50	4.00	12.59	15°		
		4.50	4.00	12.95	25°		
		5.50	2.00	10.58	15°		
		5.50	2.00	11.06	25°		
		5.50	4.00	12.58	15°		
		5.50	4.00	13.06	25°		
		6.50	2.00	10.57	15°		
		6.50	2.00	11.13	25°		
		6.50	4.00	12.57	15°		
		6.50	4.00	13.13	25°		
	Bone level Non Hex (for Ø 3.3mm implants)	3.70	1.00	8.50	15°	conic non-hexagonal internal connection	Ti Gr 5
		3.70	2.00	9.50	15°		
		3.70	4.00	11.50	15°		
	Bone level Non Hex (for Ø 3.7, 4.3, 4.8, 5.5 mm implants)	4.50	2.00	10.38	15°	conic non-hexagonal internal connection	Ti Gr 5
		4.50	2.00	10.75	25°		
		4.50	4.00	12.38	15°		
		4.50	4.00	12.75	25°		
		5.50	2.00	10.38	15°		
		5.50	2.00	10.86	25°		
		5.50	4.00	12.38	15°		
		5.50	4.00	12.86	25°		
		6.50	2.00	10.37	15°		
		6.50	2.00	10.93	25°		
		6.50	4.00	12.37	15°		
		6.50	4.00	12.93	25°		

V. INDICATIONS FOR USE

Implance Dental Implant System is indicated to use for surgical placement in the upper and lower jaw arches, to provide a root form means for single and multiple units' prosthetic appliance attachment to restore a patient's chewing function.

Implance Dental Implant can be placed 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.

Immediate loading is restricted to the anterior mandible based on four splinted-interforminal placed implants.

Implance Dental Abutment System is used with a dental implant to provide support to prosthetic restorations such as crown, bridge and overdentures in partially or fully edentulous patients. Octa Abutment models that contain an abutment post height less than 4 mm are indicated only for multi-unit loading, such as a bridge or overdenture.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Technological characteristics of the Implance Dental Implant and Implance Dental Abutment Systems are compared with the predicate devices in the following tables.

Table 4 Implance Dental Implant System Substantial Equivalence Comparison

	Implance Dental Implant System		**Primary Predicate Dentis Dental Implants System**	
510k #	K160221		K073486	
Indication	Indicated to use for surgical placement in the upper and lower jaw arches, to provide a root form means for single and multiple units' prosthetic appliance attachment to restore a patient's chewing function. Implance can be placed 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. Immediate loading is restricted to the anterior mandible based on four splintel interforminal placed implants.		Indicated for use 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 patients chewing function. Implants can be placed with a conventional two stage surgical process with an option for trans mucosal Healing or they can be placed in a single stage surgical process for immediate loading. Immediate loading is restricted to the anterior mandible based on four splintel interforminal placed implants and not indicated for single unsplinted implants.	
System Components	Dental implant and closing screw		Implant Fixtures, Protective Cap, and Implant System Surgery Tray	
Design	Threaded root-form bone or tissue level implant with hybrid and straight designs and Morse taper internal hexagon or internal octagonal abutment interface		Threaded, root-form implant design with Morse taper internal, external and submerged abutment interface	
Implant Size (mm)	Length	Diameter	Length	Diameter
	8, 10, 12, 14	3.3, 3.7, 4.3, 4.8, 5.5	7-14	3.5, 3.7, 4.1, 4.3, 4.8, 5.5, 6.0
Materials	Titanium grade 4 & 5		Titanium and its alloys	
Surface treatment	RBM surface treatment		RBM surface treatment	
Sterilization	Gamma		Gamma	
Standard for Titanium	ASTM F-67 & ASTM F-136-13		ASTM F-67 ASTM F-136	

Table 5 Implance Dental Abutment System Substantial Equivalence Comparison

	Implance Dental Abutment System	**Klockner Dental implant abutment**
510(k) #	K160221	K122988
Indication	Implance Dental Abutment System is used with a dental implant to provide support to prosthetic restorations such as crown, bridge and overdentures in partially or fully edentulous patients. Octa Abutment models that contain an abutment post height less than 4 mm are indicated only for multi-unit loading, such as a bridge or overdenture.	Klockner Dental Abutments are intended to be placed into dental implants to provide support for prosthetic reconstructions such as crowns, bridges or overdentures. The Klockner Dental Implant Abutments include healing caps, protective caps, temporary abutments, angled abutments, straight abutments, and overdentures. All abutments are intended to be used with the Klockner Dental Implant Systems, Models: Essential EC, Essential ES, Essential ECK, Essential EC 1.5, SK2 and NK2.
Material	Titanium Grade 5 (Bone Level 3,3 & 3.7 mm implants) Titanium Grade 4 ASTM F-67 (Bone Level 4,3; 4,8; 5,5 mm implants) Titanium Grade 4 ASTM F-67 (Tissue Level) Screw: Titanium Grade 5 ASTM F136	Titanium cp Titanium alloy Titanium cp +PMMA Titanium Alloy + POM C
Design	Temporary Abutment design with attached conic internal connection Final Abutment designs: Solid with cemented connection Couple, Bone Level Angled (15^0, 25^0), Multi and Synocta with cement and screw (conic, conic hexagonal, or conic octagonal) connection Octa with attached internal & external (conic hexagonal or octagonal) connection O-ring with attached conic internal connection	Temporary Abutment design With internal octagonal connection Final Abutment designs: Angled (17^0, 22^0, 30^0) with internal octagonal and external hexagonal screw connection Straight with internal octagonal screw connection Overdenture abutment with ball connection
Sterilization	Provided non-sterile	Provided non-sterile

The Implance Dental Implant System is the same or similar to the primary predicate Dentis Dental Implant System with respect to indication for use, design, material composition and surface treatment. The proposed devices have more limited indications for use than the primary predicate that does not alter the intended use for demonstration of substantial equivalence. With respect to available sizes, the Implance Dental Implant System includes a slightly smaller diameter than the predicate. The slight reduction in diameter size does not change the intended anatomical location, and the non-clinical mechanical testing provided demonstrates substantially equivalent performance.

The Implance Dental Abutment System is the same or similar with respect to indication for use, material composition and basic design features as the predicate Klockner Dental Implant Abutments. The Implance Dental Abutment System differs from the predicate with additional abutment designs.

Non-clinical performance testing consistent with the FDA's Class II Special Controls guidance document and ISO 14801 support the substantial equivalence of the Implance Dental Implant System and the Implance Dental Abutment System.

VII. PERFORMANCE DATA

Performance testing of the Implance Dental Implant and Implance Dental Abutment followed the FDA guidance Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments.

Biocompatibility

- Cytotoxicity (in vitro) – ISO 10993-5:2009
- Sensitization- ISO 10993-10:2010
- Irritation/ Intracutaneous – ISO 10993-10:2010
- Acute systemic toxicity- ISO 10993-11:2006
- Subchronic toxicity- ISO 10993-11:2006
- Genotoxicity- ISO 10993-3:2003
- Implantation- ISO 10993-6:2007

Biocompatibility testing found the materials used in the Implance Dental Implant & Implance Dental Abutment Systems are biocompatible.

Surface Treatment Analysis

The Implance Dental Implant surface undergoes a RBM treatment using calcium phosphate micro particles. SEM analysis of the RBM surface found that the surface of the Implance Dental Implant was homogeneous. Energy-dispersive X-ray spectroscopy provided elemental analysis and chemical characterization of the RBM surface after washing.

Sterilization Validation

Implance Dental Implants are sterilized using a gamma ray sterilization process that has been validated to ensure a SAL of 10^{-6}. The Implance Dental Abutment System is provided non-sterile. Sterilization of the dental abutment system is performed by the end-user following parameters used in a validated steam gravity sterilization method that achieves a SAL of 10^{-6}. The Implance Dental Implants provided sterile propose a 5-year shelf life date. The following tests were performed to show the packaging was sufficient to maintain

sterility of the dental implants over the 5-year shelf life: Adhesion Strength Control Force (Seal Strength), Package Tightness (Seal Leak) Test, and Sterility Test.

Mechanical Testing

Fatigue testing on the worst case bone level Implance Dental Implant with the worst case Implance Dental Abutment was conducted in accordance with the ISO 14801 Dentistry-Implants-Dynamic fatigue test for Endosseous dental implants. Results of the fatigue testing found that the worst case (bone level) dental implant/abutment combinations were consistent with FDA Class II Special Controls guidance and ISO 14801.

VIII. CONCLUSION

The Implance Dental Implant and Implance Dental Abutment System have the same or similar intended use, material composition, basic design, dimensions and surface treatment. Based on an a comparative assessment with the predicate devices, and the performance test data, the Implance Dental Implant and Implance Dental Abutment Systems are determined to be substantially equivalent to the predicate devices.