June 30, 2018

Zuga Medical, Inc.
Chan Wang, CEO
24400 Chagrin Blvd, Suite 250
Beachwood, Ohio 44122

Re: K171197
Trade/Device Name: Zuga™ Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: May 25, 2018
Received: June 1, 2018

Dear Chan Wang:

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.

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

7. Indications for Use Statement

510(k) Number: _K171197_

Device Name: Zuga™ Dental Implant System

Indications for Use:

The Zuga™ Dental Implant System is indicated for immediate or delayed implant placement for surgical and restorative applications in maxillary and/or mandibular arches to support prosthetic devices, such as artificial teeth, crowns, bridges, and overdentures. The Zuga™ Dental Implant System is indicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

Prescription Use __X__ OR Over-the-Counter Use_____

(Per 21 CFR 801.109)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary
K171197

Date:	29 June 2018
Sponsor:	Zuga Medical, Inc. 24400 Chagrin Boulevard Suite 250 Beachwood, OH 44122 Phone: 216.282.5910 Facsimile: 1.855.438.9842
Contact Person:	Chan Wang, CEO
Trade Names:	Zuga™ Dental Implant System
Device Classification:	Class II
Classification Name:	Implant, endosseous, root-form & abutment, implant, dental, endosseous
Regulation:	872.3640
Device Product:	DZE & NHA
Device Description:	The Zuga™ Dental Implant System includes endosseous dental implants, sealing caps, healing caps, dental implant abutments, and fixation screws in a variety of sizes to accommodate differing patient anatomy. Implantation is suitable for one-or two-stage procedures. Endosseous implants are bone level, self-tapping, root-form, threaded. The threaded surface is blasted, then passivated. Sizematched anterior and posterior abutments are offered. These are fastened to the implant using a fixation screw. Sealing caps and healing caps provide protection to the abutment connection threads during endosseous and gingival healing. The implants are provided sterile, the remaining components must be sterilized prior to use.

Zuga Medical is making no claims regarding pyrogenicity.

Implant	Material	Cold Worked Ti Grade 4 as described in ASTM F67
	Diameter (mm)	3.5, 4.3, 5.0
	Length (mm)	8.00, 9.00, 10.00, 11.00, 12.00, 13.00, 14.00, 15.00, 16.00, 17.00
	Angulation	-
	Description	Endosseous Implant
Ti Abutment	Material	Cold Worked Ti Grade 4 as described in ASTM F67
	Diameter (mm)	4.75, 5.50, 6.25, 7.00
	Post Height (mm)	4.00, 5.50, 7.00
	Angulation	-
	Description	Straight Titanium Abutment
Angled Abutment	Material	Cold Worked Ti Grade 4 as described in ASTM F67 or Cold Worked Ti Grade 5
	Diameter (mm)	3.5, 4.3, 5.0
	Post Height (mm)	8.50, 9.50, 10.50, 11.50
	Angulation	15, 25
	Description	Angled Titanium Abutment
Ball Abutment	Material	Titanium CP Grade 4 Cold Worked or Annealed
	Diameter (mm)	3.5
	Gum Height (mm)	1.00, 2.00, 3.00, 4.00, 5.00
	Angulation	-
	Description	Abutment for overdenture restoration
Removable Denture Abutment	Material	Titanium CP Grade 4 Cold Worked or Annealed
	Diameter (mm)	3.85
	Gum Height (mm)	1.00, 2.00. 3.00, 4.00, 5.00

	Angulation	-
	Description	Abutment for overdenture restoration
Hybrid Abutment	Material	ZIY and Cold Worked Ti Grade 4 as described in ASTM F67
	Diameter (mm)	4.25, 4.30, 5.05, 5.50
	Length (mm)	10.50
	Angulation	-
	Description	Titanium and Zirconium abutment
Multi-Unit Abutment	Material	Cold Worked Ti Grade 4 as described in ASTM F67
	Diameter (mm)	4.00, 4.80
	Gum Height (mm)	1.50, 2.50, 3.50, 4.50
	Angulation	0, 17, 30
	Description	Titanium Abutment to be used with multiple prosthetic devices
Healing Cap	Material	Titanium CP Grade 4 Cold Worked or Annealed
	Diameter (mm)	4.85, 5.65, 6.35
	Post Height (mm)	3.00, 5.00, 7.00
	Angulation	-
	Description	Protects implant during healing.
Fixation Screw	Material	Titanium 6AL-4V per ASTM F136
	Diameter (mm)	2.35
	Length (mm)	7.50
	Angulation	-
	Description	Fastens abutment to implant
Sealing Cap	Material	Titanium CP Grade 4 Cold Worked or Annealed
	Diameter (mm)	2.75
	Length (mm)	5.00
	Angulation	-
	Description	Protects implant during healing.

Indications for Use: The Zuga™ Dental Implant System is indicated for immediate or delayed implant placement for surgical and restorative applications in maxillary and/or mandibular arches to support prosthetic devices, such as artificial teeth, crowns, bridges and overdentures. The Zuga™ Dental Implant System is indicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

Predicate Devices: Zuga™ Dental Implant System – K122664
T-Plus Implant Tech. Co., Ltd. ST Internal Fixture System – K152787
OCO Biomedical Fixed Solid O-Ball Abutment – K090174
Nobel Biocare AB NobelActive Multi-Unit Abutment – K072570
Reliadent Dental Implant System – K043428, K061323
Biomet 3i Certain System – K0100724
KAT Implants System Implants, KAT Implants System Implant Abutment – K083544
KAT Implants System Implants, KAT Implants System Straight Abutments – K101201
Southern Implants Endosseous Dental Implant System – K070841, K071161

Technological Characteristics: The fundamental scientific technology of the Zuga™ Dental Implant System is the same as previously cleared devices as shown below, (i.e. the Zuga design features are common to one or more of the predicates):

Zuga Implant System						
	Subject Device	**Primary Predicate Device**	**Reference Devices**			
Company	**Zuga Medical**	**Zuga Medical**	**Reliadent**	**Biomet 3i**	**KAT**	**Southern Implants**
510(k) Number	New Device	K122664	K043428, K061323	K100724	K083544, K101201	K070841, K071161

Intended Use	The Zuga™ Dental Implant System is indicated for immediate or delayed implant placement for surgical and restorative applications in maxillary and/or mandibular arches to support prosthetic devices, such as artificial teeth, crowns, bridges, and overdentures. The Zuga™ Dental Implant System is indicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading.	The Zuga™ Dental Implant System is indicated for immediate or delayed implant placement for surgical and restorative applications in maxillary and/or mandibular arches to support prosthetic devices, such as artificial teeth, crowns, bridges, and overdentures. The Zuga™ Dental Implant System is indicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading.	The Reliadent Dental Implant System is indicated for immediate or delayed surgical and restorative application for placement in maxillary and /or mandibular arches to support prosthetic devices, such as artificial teeth, crowns, bridges and overdentures for the patient.	BIOMET 3i Dental Implants are intended for surgical placement in either jaw and used for anchoring or supporting single- and multiple-unit prostheses. BIOMET 3i Dental Implants can be immediately loaded when primary stability and proper occlusion have been established.	KAT Implant System Dental Implants are indicated for restoration of edentulous maxilla and mandible, to provide support for removable dentures, fixed bridges, or to be used as a single tooth replacement. Single or splinted implants can be immediately loaded if good primary stability and appropriate occlusal loading are achieved. The implants can be placed in extraction sites or healed alveolar ridges. Immediate loading may not be appropriate in Type IV bone due to difficulty in achieving Primary stability.	The NSI Implant System is intended to be implanted in the upper or lower jaw arches to provide support for fixed or removable dental prostheses in a single tooth, partially edentulous prostheses, or full arch prostheses. It further adds the option for immediate loading on single and splinted multiple unit restorations when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function.

Material of Manufacture:	Titanium, Titanium Alloy	Titanium, Titanium Alloy	Titanium	Titanium, Titanium Alloy	Titanium Alloy	Titanium
Endosseous Implant						
Endosseous Implant Design	Root-form, Straight and tapered	Root-form, Straight	Root-form, Straight	Root-form, Straight and tapered	Root-form, Straight and tapered	Root-form, Straight and tapered
Method of stabilization	Threaded fixation	Threaded fixation	Threaded fixation	Threaded fixation	Threaded fixation	Threaded fixation
Range of Diameters	3.5 – 5.5mm	3.5 – 5.5mm	3.0 – 5.5mm	3.25 – 6mm	2.5 -8mm	-----
Range of Lengths	8 – 17 mm	8 – 17 mm	8 – 16mm	8.5 – 20mm	6 -14mm	-----
Surface Treatment	Al_20_3 blasted, passivated	Al_20_3 blasted, passivated	Titanium blasted and acid etched	acid etched	Al_20_3 blasted, passivated	Al_20_3 blasted
Color-coding	Seating surface or None	Seating surface	Anodized seating	Seating surface	None	None
Sterilization	Sterile, Gamma radiation	Sterile, Gamma radiation	Sterile, Gamma radiation	Sterile, Gamma radiation	Sterile, Radiation	Sterile, Gamma radiation
Endosseous Implant Abutment						
Abutment Design	Standard	Standard	Standard, Angled	-----	Standard, Angled	Standard, Angled
Sterilization	Non-sterile	Non-sterile	Non-sterile	-----	Non-sterile	-----
Connection to Implant	Hex alignment, screw attachment	Hex alignment, screw attachment	Hex alignment, screw attachment	-----	Indexing key alignment, 1.5˚ locking taper, screw attachment	-----
Color-coding	Connection interface or none	Connection interface	Connection interface	-----	-----	-----

Angled Abutment			
	Subject Device	**Primary Predicate Devices**	**Reference Device**

System:	Zuga	T-Plus Implant Tech. Co., Ltd.	MegaGen Co., Ltd
Device Name	Zuga Dental Implant System	ST Internal Fixture System	Ex Feel Dental Implant System
510(k) Number	New Device	K152787	K052369
Intended Use	The Zuga™ Dental Implant System is indicated for immediate or delayed implant placement for surgical and restorative applications in maxillary and/or mandibular arches to support prosthetic devices, such as artificial teeth, crowns, bridges, and overdentures. The Zuga™ Dental Implant System is indicated 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 acheived 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 state surgical procedure.
Abutment Diameters, mm	3.5, 4.3, 5.0	4.0, 5.0, 6.0	4.0, 5.0, 6.0
Abutment Cuff(Gum) Height, mm	1.5, 2.5, 3.5, 4.5	1.0, 2.0, 3.0, 4.0, 5.0	2.0, 4.0
Angulation Range	15˚, 25˚	15˚, 25˚	15˚, 25˚
Implant to Abutment Connection	Internal Hexagon	Internal Hex Connection	Internal and External Hex
Abutment Fixation	Abutment Screw	-	-
Abutment Material	Titanium Alloy	C.P. Titanium and Titanium Alloy	C.P. Titanium and Titanium Alloy
Sterilization	Delivered Non-Sterile	Delivered Non-Sterile	Delivered Non-Sterile
Reusable	No	No	No

Ball Abutment				
	Subject Device	**Primary Predicate Device**	**Reference Devices**	
Company	**Zuga Medical**	**OCO Biomedical**	**Nova Implants Ltd.**	**SGS International Ltd.**
Device Name	Zuga Dental Implant System - Ball Abutment	Fixed Solid O-Ball Abutment	Ball Attachment BAT	Overdenture Ball Attachment S3
510(k) Number	New Device	K090174	K150363	K133362
Intended Use	The Zuga™ Dental Implant System is indicated for immediate or delayed implant placement for surgical and restorative applications in maxillary and/or mandibular arches to support prosthetic devices, such as artificial teeth, crowns, bridges, and overdentures. The Zuga™ Dental Implant System is indicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading.	The TSI and ERI Dental Implants are artificial root structures intended for permanent surgical implantation in the bone for the purpose of single or multiple tooth replacements (splinted or free standing), or for stabilization of a prosthetic system, such as artificial teeth in order to restore the patient's chewing function. The TSI and ERI can be placed in the anterior or posterior mandible/maxilla for immediate or delayed loading purposes.	NOVA® Dental Implants System is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. NOVA® Dental Implants System is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading.	SGS® Dental Implants System is intended for surgical placement in the maxillary and/or mandibular arch to support crowns, bridges, or overdentures in edentulous or partially edentulous patients. SGS® Dental Implants System may be immediate loading when good primary stability is achieved and with appropriate occlusal loading.
Abutment Heights, mm	1, 2, 3, 4, 5	0, 2, 3, 4	1, 2, 3, 4, 5 ,6	1, 2, 3, 4, 5, 6
Implant to Abutment Connection	External Square	External Square	Internal Hex	Internal Hex, Overdenture rest.

Abutment Fixation	Screw Retained	Screw Retained	Screw Retained	-
Abutment Material	Titanium Alloy	Titanium Alloy	Titanium Alloy	Titanium Alloy
Sterilization	Delivered NonSterile	-	-	-
Reusable	No	No	No	No

Multi-Unit Abutment				
	Subject Device	**Primary Predicate Device**	**Reference Device**	
Company	**Zuga Medical**	**Nobel Biocare AB**	**Biodenta Swiss AG**	**Biomet 3i**
Device Name	Zuga Dental Implant System – Multi-Unit Abutment	NobelActive Multi-Unit Abutment	Biodenta Dental Implant System-Multi-Use Abutment	Low Profile Abutment
510(k) Number	New Device	K072570	K123491	K092341
Intended Use	The Zuga™ Dental Implant System is indicated for immediate or delayed implant placement for surgical and restorative applications in maxillary and/or mandibular arches to support prosthetic devices, such as artificial teeth, crowns, bridges, and overdentures. The Zuga™ Dental Implant System is indicated for immediate loading when good primary stability is	NobelActive Multi-Unit Abutment is a pre-manufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation.	Biodenta Dental Implant System Multi-Use Abutments are intended for terminal or intermediate abutment support for fixed or removable crown, bridgework, and to retain overdentures.	Biomet 3i Low Profile Abutments are intended for use as accessories to endosseous dental implant to support a prosthetic device in a partially or completely edentulous patient. A dental abutment is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The prosthesis is screw retained to the abutment.

	achieved and with appropriate occlusal loading.			
Restorations	Screw Retained	Screw Retained	Screw Retained	Screw Retained
Abutment Type	Straight & Angled	Straight & Angled	Straight & Angled	Straight & Angled
Abutment Angle	0˚,17˚,30˚	0˚,17˚,30˚	0˚,18˚,30˚	0˚,17˚,30˚
Implant to Abutment Connection	Internal Hexagon	Internal Hexagon	Internal Hexagon	Internal Hexagon
Abutment Fixation	Abutment Screw	Abutment Screw	Abutment Screw	Abutment Screw
Compatible Implants Diameter	3.5mm	3.5mm	3.5mm	3.25mm
	4.0mm	4.3mm	4.1mm	4.0mm
	4.3mm	5.0mm	4.8mm	5.0mm
	5.0mm			6.0mm
Abutment Cuff(Gum) Height	1.5-4.5mm (0˚)	1.5-4.5mm (0˚)	2.0-5.0mm (0˚)	1.0-4.0mm (0˚)
	2.5–3.5mm (17˚)	2.5–3.5mm (17˚)	2.2–5.2mm (18˚)	2.0–4.0mm (17˚)
	3.5-4.5mm (30˚)	3.5-4.5mm (30˚)	2.0-5.0mm (30˚)	3.0-5.0mm (30˚)
Abutment Material	Titanium Alloy	Titanium Alloy	Titanium Alloy	Titanium Alloy
Sterilization	Delivered NonSterile	Delivered NonSterile	Delivered NonSterile	Delivered Non-Sterile
Reusable	No	No	No	No

Removable Denture Abutment		
	Subject Device	**Primary Predicate Device**
Company	**Zuga Medical**	**Zest Anchors, Inc.**
Device Name	Zuga Dental Implant System - Removable Denture Abutment	LOCATOR Implant Anchor Abutment for Endosseous Dental Implant
510(k) Number	New Device	K072878

Intended Use	The Zuga™ Dental Implant System is indicated for immediate or delayed implant placement for surgical and restorative applications in maxillary and/or mandibular arches to support prosthetic devices, such as artificial teeth, crowns, bridges, and overdentures. The Zuga™ Dental Implant System is indicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading.	The LOCATOR Implant Anchor Abutment for Endosseous Dental Implants is appropriate for use with overdentures or partial dentures retained in whole or in part by endosseous implants in the mandible or maxilla.
Abutment Diameters, mm	3.85	3.25 to 6.5
Abutment Angle	Straight	Straight
Abutment/Implant Interface	Screw Retention	Conical, External Hex, Internal Hex, Internal Multi Lobe
Divergence Allowance	Maximum 40° divergence between two implant constructs, with each individual implant/abutment construct having no more than 20° correction.	20˚/40˚
Prosthesis Attachment Type	Nylon Male retention cap	Nylon male retention cap
Abutment Material	Titanium Grade 4	Ti-6Al-4V ELI
Prosthetic Retention Component	Nylon	Nylon

Hybrid Abutment

System:	**Zuga™ Dental Implant System - Hybrid Abutment**	**K122664 Zuga™ Dental Implant System – Primary Predicate**	**K143011 2014 InterActive/ SwishActive System - Reference Predicate**
ENDOSSEOUS IMPLANT ABUTMENT			
Material of Manufacture:			
Abutment	NA	Titanium	NA
Abutment Base	Titanium	NA	Titanium
Abutment Upper	Yttria-stabilized Zirconia	NA	Yttria-stabilized Zirconia
Connection	Cement	NA	Cement
Design:	Straight	Straight	Straight, Angled, or Modified
Sterilization	Non-Sterile	Non-Sterile	Non-Sterile
Connected to Implant	Hex alignment, screw attachment	Hex alignment, screw attachment	Hex alignment, screw attachment
Implant Platforms it can be used with	3.5, 4.3, 5.0, 5.5	3.5, 4.3, 5.0, 5.5	Not known

Performance Data:

Static fatigue tests and dynamic fatigue tests were performed per ISO 14801 and FDA Guide: Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments. The worst case scenarios for the Zuga™ Dental Implant System were tested. The results show that the Zuga™ Dental Implant System has sufficient mechanical strength for the intended clinical application.

Cytotoxicity testing was performed per ISO 10993-5 and The United States Pharmacopeia & National Formulary (USP <87>). The worst case scenarios for the Zuga™ Dental Implant System were tested. The results showed that the Zuga™ Dental Implant System received a passing score and is thus acceptable for clinical application.

Sterility tests performed under ISO 10993 yielded no difference in performance between the Zuga™ Dental Implant System and the predicate device. Sterile subject devices were evaluated in accordance to ISO 11137-1 and 11137-2. "End-user" sterilized devices were validated according to ISO 17665-1 and 17665-2.

Further, LAL (Limulus Amebocyte Lysate) bacterial endotoxin tests performed under ISO 10993 on the subject device yielded a EU/Device value that was less than the established acceptance criteria of 20 EU/Device for medical devices not intended to contact cerebrospinal fluid.

Shelf life tests are performed under ISO 11607 for evaluating seal strength of flexible barrier materials and porous medical packaging used in the sterile packaged products in the Zuga™ Medical Dental Implant System. Test results established the shelf life to be five years provided the sterile seal is not breached. The subject device is a titanium alloy, non-mechanical, non-active device, therefore, degradation in performance characteristics is not likely over the established shelf-life period. Special storage conditions are not required for the device, as ambient storage conditions are not expected to adversely affect the safety or efficacy of the device.

In accordance with the United States Pharmacopeial Convention, Inc. USP <85>, Bacterial Endotoxins Tests (BET), also known as Limulus Amebocyte Lysate (LAL) tests, is made to determine that

the device meets pyrogenicity limit specifications. These Bacterial Endotoxins Tests (BET) are run in accordance with the kinetic turbidimetric method as follows: Representative samples are selected from each sterilization batch. Each sterilization batch consists of multiple manufacturing lots. The sampling plan consists of selecting 3% of the batch up to a maximum of 10 samples to be pooled for testing. The Testing limit is 20 EU/device because, according to USP ,161> the limit for a device in contact with the circulatory system or lymphatic system is 20 EU/device.

Conclusion:

The Zuga™ Dental Implant System device possesses the same intended use and technological characteristics as the predicate devices. This with the information provided in the submission permit the conclusion that the Zuga™ Dental Implant System is substantially equivalent to the predicate devices.