### 510(k) Summary

APR 1 6 2014

Sponsor:

Sterngold Dental, LLC

23 Frank Mossberg Drive Attleboro, MA 02703

Contact:

Maria Rao, QA/RA Director

Ph: 508-226-5660 ext 1206

Trade Name:

ORA Implant Abutments System

Common Name:

Implant Abutments

Classification Name: Endosseous Dental Implant Abutment

Chastication (and) Endospeous Dental Implant (fouthful)

Classification: According to Section 513 of the Federal Food, Drug, and

Cosmetic Act, the device classification is Class II

Product Code:

NHA (21CFR 872.3630)

### Legally Marketed Device to which Equivalence is claimed (Predicate Devices):

Predicate Device(s): K900099, K130183, K132814.

K900099 The O-Ring System – ORS

K130183 SFI Bar® Implant Abutments for 7 Platforms K132814 SFI Bar® Implant Abutments for 9 Platforms

### **Description of Device:**

The ORA Implant Abutment is a precision machined ball shaped abutment that connects a compatible dental implant system with a removable partial or complete overdenture. The implant abutment is screwed into the dental implant. Connection to and retention of a denture is provided by a rubber o-ring, which may or may not be held within a metal housing. There are two color o-rings, a red processing o-ring and a white final o-ring.

The retaining ring (metal housing) comes with the red o-ring (which is a firm rubber) inside. The retaining ring (metal housing) with the red o-ring is pushed over the wide part of the ball until seated. The stiffness of the red o-ring holds the housing in position. Any exposed areas of the abutment are blocked out so that only the metal housing is exposed. The retaining ring (metal housing) is then processed into the denture. After the material has cured, the denture is removed. The red o-ring is pulled out of the metal housing and the white o-ring is inserted into its place. The white o-ring is more flexible making insertion and removal easier. The bottom portion of the abutment (cuff area to end of threads) is an exact replica of the SFI Implant Abutments previously cleared by K130183 and K132814.

ORA Implant Abutments are available in sixteen different platforms and each platform is compatible with one or more implant types. Table 1 demonstrates implant/abutment compatibility. The difference between each platform is the internal connection with the specific implant. This connection has been previously cleared by K130183 and K132814—SFI Implant Abutments.

The devices are supplied non-sterile, and there is no shelf life.

#### Intended Use of the Device:

The ORA Implant Abutment System is indicated for use with dental implants to support and/or retain removable dental prostheses in the treatment of partially or totally edentulous patients to restore chewing function. The abutment screws directly into endosseous implants or they screw into SFI Abutments which are screwed into endosseous implants.

Implant Brand	Model
Nobel Biocare Brånemark System	3.3 Fixture, 3.75 Fixture, 4.0 Fixture, 5.0 Fixture (Old Version), 3.75 MkII Self-tapping Fixture, 4.0
•	MkII Self-tapping Fixture
Sterngold-ImplaMed	3.3 Hex Cylinder, 4.0 Hex Cylinder, 3.75 Standard Hex Screw, 3.75 Self-tapping "SST" Hex Screw, 4.0 Standard Hex Screw, 4.0 Self-tapping "SST" Hex Screw, 3.75 RP Acid Etched, 4.0 RP Acid Etched, 5.0 RP Acid Etched, 4.1 Stern IC (4.8 head), 3.3 Stern IC (4.8 head)
Nobel Biocare (Steri-Oss®)	3.8 HL Cylinder, 3.8 HL Threaded, 4.5 HL Threaded, 3.5 NobelReplace™, Replace® Select (NP), 4.0 NobelReplace Straight, (RP), 4.3Replace®Select&NobelReplace™ (RP)
Keystone (Lifecore)	3.75 Restore® Self-tapping Screw, 4.0 Restore® Self-tapping Screw, 3.75 Restore® External Hex Screw, 4.0 Restore® External Hex Screw, 4.0 Restore® External Hex Cylinder, 4.2 Sustain® External Hex Cylinder, 3.75 Sustain® External Hex Screw, 4.0 Sustain® External Hex Screw, 4.2 Sustain® External Hex MC Cylinder, Stage-1TM (3.3 and 4.0 fixtures)
3i Implant Inovations	3.25 External Hex Miniplant®, 3.25 ICE <sup>™</sup> Miniplant®, 3.25 OSSEOTITE® Miniplant®, 3.3 Cylinder Miniplant®, 3.3 External Hex Cylinder, 3.75 ICE <sup>™</sup> Self-tapping, 3.75 OSSEOTITE®, 3.75 Self-tapping Threaded, 3.75 Standard Threaded, 4.0 External Hex Cylinder, 4.0 ICE <sup>™</sup> Self-tapping, 4.0 OSSEOTITE®, 4.0 Standard Threaded, 4.25 External Hex Cylinder, TG OSSEOTITE® (4.8 Platform), 4.0 OSSEOTITE® Certain <sup>™</sup> , 4.0 OSSEOTITE® NTCertain <sup>™</sup> , 4.0 OSSEOTITE®CERTAIN PREVAIL, 5.0 Osseotite® Certain, 5.0 Osseotite® NT Certain, 5.0 Osseotite®Certain Prevail
IMTEC Corporation®	3.3 Universal Flare Cylinder, 3.75 Universal Self-tapping, 3.75 Universal Self-tapping Coated, 4.0 Spike Cylinder, 4.0 Universal Cylinder
Interpore IMZ <sup>TM</sup>	3.3 Hex Cylinder, 3.75 Self-tapping Threaded, 4.0 Hex Cylinder, 4.0 Self-tapping Threaded, 4.25 Hex Cylinder
Osstem	4.1 US II, III, II Plus, III Plus, SS II, III (4.8 head)
Zimmer Dental	3.5 Bio-Vent® X <sup>IM</sup> , 3.75 Swede-Vent <sup>IM</sup> Conical Neck CST, 3.75 Swede-Vent <sup>IM</sup> Standard, 4.0 Swede-Vent <sup>IM</sup> Standard, 4.0 Bio-Vent® X <sup>IM</sup> , 3.25 Micro-Vent® (3.5 head), 3.3 Screw-Vent® (3.5 head), 3.5 Bio-Vent® (3.5 head), 3.7 Screw-Vent® (3.5 head), 3.75 Screw-Vent® (3.5 head), 4.3 Core-Vent® (3.5 head), 4.25 Micro-Vent® (4.5 head), 4.5 Bio-Vent® (4.5 head), 4.7 Screw-Vent® (4.5 head), 5.3 Core-Vent® (4.5 head), 3.7 Tapered Swiss Plus <sup>TM</sup> (4.8 platform), 4.8 Tapered Swiss Plus <sup>TM</sup> 4.1 Straight Swiss Plus <sup>TM</sup> , 4.8 Straight Swiss Plus <sup>TM</sup>
Zimmer (Calcitek®, Centerpulse)	3.75 ThreadLoc <sup>IM</sup>
Straumann	ITI TE <sup>™</sup> 3.3 (4.8 head), ITI 3.3 Std & Std Plus (4.8 head), ITI TE <sup>™</sup> 4.1 (4.8 head), ITI 4.1 Std. & Std. Plus (4.8 head), ITI, 4.8 Std. & Std. Plus (4.8 head)
Biolok International	4.5 Silhouette Screw, 4.0 Micro-Lok Screw, 4.0 Micro-Lok Cylinder, 3.75 Micro-Lok Screw, 3.3 Micro-Lok Cylinder
Bud	3.25 Bud Screwvent, 3.75 Bud Screwvent
INNOVA	4.1 ENDOPORE® External Connection, 4.0 ENTEGRATM External Connection
OIC	3.0 Osteo Standard ST, 3.25 Osteo Standard ST, 3.75 Osteo Standard ST
MIS IMPLANTS	3.3mm Internal Hex, 3.75mm Internal Hex, 4.20mm Internal Hex, 5.0mm Internal Hex
BioHorizons®	3.5 Internal, 4.0 Internal, 4.5 Internal, 3.5 Single Stage, 4.5 Single Stage  Legacy 3.5mm, Legacy 4.5mm, RePlant™ 4.3mm, RePlant™ 3.5mm, 3.7mm ScrewPlant, 4.7mm
Implant Direct	ScrewPlant
Minimatic/Stryker	3.3 External Hex Cylinder, 3.75 External Hex Screw, 4.0 External Hex Cylinder, 4.0 External Hex Screw, 4.75 External Hex Screw, 5.0 External Hex Cylinder
Straumann	Straumann Bone Level RC, Blue Sky Bio Square Taper RC
Straumann	Straumann Bone Level NC, Blue Sky Bio Square Taper NC
Ankylos	Ankylos
Nobel Biocare	Nobel Replace WP, Nobel Replace Select WP, NobelSpeedy Replace WP, Implant Direct 5.0 RePlant, BlueSky Bio 5.0 Trilobe
Nobel Biocare	Nobel Conical Connection RP
Nobel Biocare	Nobel Conical Connection NP, Blue Sky Bio Max
Astra Dental	Astra 4.5 / 5.0, Blue Sky Bio Conus 12 4.5 / 5.0
Astra Dental	Astra 3.5 / 4.0, Blue Sky Bio Conus 12 3.5 / 4.0
Zimmer Dental	Zimmer TSV 5.7mm, Implant Direct Legacy 5.7, BioHorizon 5.7

### **Technical Characteristics:**

The proposed implant abutments are substantially equivalent to the currently marketed predicate devices. The intended use, basic design, fundamental operating principles and manufacturing procedures are the same as the predicate devices.

Attribute	Candidate	Predicate Device	Predicate Device
	The ORA Implant Abutment Sterngold Dental, LLC	The O-Ring System – ORS Attachments International, Inc. K900099	SFI Implant Abutments Sterngold Dental, LLC K130183, K132814
Design/Construction	Machined, screw-retained	Machined, screw-retained	Machined, screw-retained
Anatomical Site	Oral Cavity	Oral Cavity	Oral Cavity
Device Material	Wrought Titanium-6AL-4 Vanadium ELI Alloy	Wrought Titanium-6AL-4 Vanadium ELI Alloy	Wrought Titanium-6AL-4 Vanadium ELI Alloy
Indications for Use	Indicated for use with dental implants to support and/or retain removable dental prostheses in the treatment of partially or totally edentulous patients to restore chewing function. The abutment screws directly into endosseous implants.	The ORS Implant Abutments are intended for use with dental implants as a support or attachment for prosthetic restoration. The abutment screws directly into the implant.	The SFI-Bar® Implant Abutments are indicated for use with dental implant bodies/fixtures to support and /or retain removable dental prostheses for partially or totally edentulous patients to restore chewing function.
Operating Principle/ Basic Design	Abutment Implant connection: Screw fixation	Abutment Implant connection: Screw fixation	Abutment Implant connection: Screw fixation
	Connecting principle to overdenture: Retentive system	Connecting principle to overdenture: Retentive system	Connecting principle to overdenture: Retentive system
	Cleaning procedures for patient: Common procedure for oral hygiene	Cleaning procedures for patient: Common procedure for oral hygiene	Cleaning procedures for patient: Common procedure for oral hygiene
·	Patient handling: Common cleaning and insertion of denture	Patient handling: Common cleaning and insertion of denture	Patient handling: Common cleaning and insertion of denture
Packaging, materials and processes	Produced in a controlled CNC machine process, previously validated Packaging: Pouch Non-sterile	Produced in a controlled CNC machine process, previously validated Packaging: Pouch Non-sterile	Produced in a controlled CNC machine process, previously validated Packaging: Pouch Non-sterile
Cuff Sizes	0.4, 1.0, 1.25, 2.0, 3.0, 4.0, 5.0mm	1.0, 2.0, 3.0, 4.0, 5.0, 6.0, 7.0mm	1.0, 1.5,1.75, 2.0, 2.2, 2.5, 3.0, 3.5, 4.0, 4.5, 5.0, 5.5mm
Prosthetic Connection	RP, Conical, NP, WP, 3.5 Head, 4.0 Head, 4.1 Head, 4.5 Head, 4.8 Head	RP, Conical, NP, WP, 3.5 Head, 4.0 Head, 4.1 Head, 4.5 Head, 4.8 Head	RP, Conical, NP, WP, 3.5 Head, 4.0 Head, 4.1 Head, 4.5 Head, 4.8 Head

#### Performance Date:

Application and functional testing have been conducted to evaluate the performance characteristics of the ORA Implant Abutments. The test methods used were the same as in predicate devices. Testing has shown that the ORA Implant Abutments included in this application are equivalent in performance characteristics to its predicate devices.

### Safety and Effectiveness / Conclusion:

Non-clinical test data was used to support the substantially equivalence claim. Clinical testing was not necessary. The non-clinical testing consisted of tolerance analysis of platforms to identify worst case test samples. Fatigue testing was not done as the basic design is the same as the predicate devices. The summary of technological characteristics as well as application and functional testing indicate that the device is substantially equivalent to the declared predicate devices.



#### 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 16, 2014

Sterngold Dental, LLC
Ms. Maria Rao
Director, Quality and Regulatory Affairs
23 Frank Mossberg Drive
Attleboro, MA 02703

Re: K133791

Trade/Device Name: ORA Implant Abutments System

Regulation Number: 21 CFR 872.3630

Regulation Name: Endosseous Dental Implant Abutment

Regulatory Class: II Product Code: NHA Dated: March 17, 2014 Received: March 19, 2014

Dear Ms. Rao:

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 <u>Federal Register</u>.

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

Page 2 - Ms. Rao

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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <a href="http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm">http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm</a>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Sterngold Dental, LLC Abbreviated 510(k) Premarket Notification April 14, 2014 ORA Implant Abutment System

510(k) Number (if known): <u>1(133791)</u>

Device Name: ORA Implant Abutment System

#### Indications for Use:

The ORA Implant Abutment System is indicated for use with dental implants to support and/or retain removable dental prostheses in the treatment of partially or totally edentulous patients to restore chewing function. The abutment screws directly into endosseous implants or they screw into SFI Abutments which are screwed into endosseous implants.

Implant Brand	Model
Nobel Biocare Brånemark System	3.3 Fixture, 3.75 Fixture, 4.0 Fixture, 5.0 Fixture (Old Version), 3.75 MkII Self-tapping Fixture, 4.0 MkII Self-tapping Fixture
Sterngold-ImplaMed	3.3 Hex Cylinder, 4.0 Hex Cylinder, 3.75 Standard Hex Screw, 3.75 Self-tapping Hex Screw, 3.75 Self-tapping "SST" Hex Screw, 4.0 Standard Hex Screw, 4.0 Self-tapping "SST" Hex Screw, 4.0 Self-tapping "SST" Hex Screw, 4.0 Self-tapping "SST" Hex Screw, 5.0 RP "SST" Hex Screw, 3.75 RP Acid Etched, 4.0 RP Acid Etched, 5.0 RP Acid Etched, 4.1 Stern IC (4.8 head), 3.3 Stern IC (4.8 head)
Nobel Biocare (Steri-Oss®)	3.8 HL Cylinder, 3.8 HL Threaded, 4.5 HL Threaded, 3.5 NobelReplace™, Replace® Select (NP), 4.0 NobelReplace Straight, (RP), 4.3Replace®Select&NobelReplace™ (RP)
Keystone (Lifecore)	3.75 Restore® Self-tapping Screw, 4.0 Restore® Self-tapping Screw, 3.75 Restore® External Hex Screw, 4.0 Restore® External Hex Screw, 4.0 Restore® External Hex Cylinder, 4.2 Sustain® External Hex Cylinder, 3.75 Sustain® External Hex Screw, 4.0 Sustain® External Hex Screw, 4.2 Sustain® External Hex MC Cylinder, Stage-1TM (3.3 and 4.0 fixtures)
3i Implant Inovations	3.25 External Hex Miniplant®, 3.25 ICE™ Miniplant®, 3.25 OSSEOTITE® Miniplant®, 3.3 Cylinder Miniplant®, 3.3 External Hex Cylinder, 3.75 ICE™ Self-tapping, 3.75 OSSEOTITE®, 3.75 Self-tapping Threaded, 3.75 Standard Threaded, 4.0 External Hex Cylinder, 4.0 ICE™ Self-tapping, 4.0 OSSEOTITE®, 4.0 Standard Threaded, 4.25 External Hex Cylinder, TG OSSEOTITE® (4.8 Platform), 4.0 OSSEOTITE® Certain™, 4.0 OSSEOTITE® NTCertain™, 4.0 OSSEOTITE®CERTAIN PREVAIL, 5.0 Osseotite® Certain, 5.0 Osseotite® NT Certain, 5.0 Osseotite®Certain Prevail
IMTEC Corporation®	3.3 Universal Flare Cylinder, 3.75 Universal Self-tapping, 3.75 Universal Self-tapping Coated, 4.0 Spike Cylinder, 4.0 Universal Cylinder
Interpore IMZ <sup>1M</sup>	3.3 Hex Cylinder, 3.75 Self-tapping Threaded, 4.0 Hex Cylinder, 4.0 Self-tapping Threaded, 4.25 Hex Cylinder
Osstem	4.1 US II, III, II Plus, III Plus, SS II, III (4.8 head)
Zimmer Dental	3.5 Bio-Vent® X <sup>IM</sup> , 3.75 Swede-Vent <sup>IM</sup> Conical Neck CST, 3.75 Swede-Vent <sup>IM</sup> Standard, 4.0 Swede-Vent <sup>IM</sup> Standard, 4.0 Bio-Vent® X <sup>IM</sup> , 3.25 Micro-Vent® (3.5 head), 3.3 Screw-Vent® (3.5 head), 3.5 Bio-Vent® (3.5 head), 3.7 Screw-Vent® (3.5 head), 3.75 Screw-Vent® (3.5 head), 4.3 Core-Vent® (3.5 head), 4.25 Micro-Vent® (4.5 head), 4.5 Bio-Vent® (4.5 head), 4.7 Screw-Vent® (4.5 head), 5.3 Core-Vent® (4.5 head), 3.7 Tapered Swiss Plus <sup>TM</sup> (4.8 platform), 4.8 Tapered Swiss Plus <sup>TM</sup> 4.1 Straight Swiss Plus <sup>TM</sup> , 4.8 Straight Swiss Plus <sup>TM</sup>
Zimmer (Calcitek®, Centerpulse)	3.75 ThreadLoc <sup>TM</sup>
Straumann	ITI TE <sup>TM</sup> 3.3 (4.8 head), ITI 3.3 Std & Std Plus (4.8 head), ITI TE <sup>TM</sup> 4.1 (4.8 head), ITI 4.1 Std. & Std. Plus (4.8 head), ITI, 4.8 Std. & Std. Plus (4.8 head)
Biolok International	4.5 Silhouette Screw, 4.0 Micro-Lok Screw, 4.0 Micro-Lok Cylinder, 3.75 Micro-Lok Screw, 3.3 Micro-Lok Cylinder
Bud .	3.25 Bud Screwvent, 3.75 Bud Screwvent
INNOVA	4.1 ENDOPORE® External Connection, 4.0 ENTEGRATM External Connection
OIC	3.0 Osteo Standard ST, 3.25 Osteo Standard ST, 3.75 Osteo Standard ST
MIS IMPLANTS	3.3mm Internal Hex, 3.75mm Internal Hex, 4.20mm Internal Hex, 5.0mm Internal Hex
BioHorizons®	3.5 Internal, 4.0 Internal, 4.5 Internal, 3.5 Single Stage, 4.5 Single Stage  Legacy 3.5mm, Legacy 4.5mm, RePlant™ 4.3mm, RePlant™ 3.5mm, 3.7mm ScrewPlant, 4.7mm
Implant Direct	Legacy 3.5mm, Legacy 4.5mm, RePlant 4.5mm, RePlant 5.5min, 3.7min Sciewhalt, 4.7min

### Records processed under FOIA Request # 2016-1128; Released by CDRH on 09-06-2016

Sterngold Dental, LLC Abbreviated 510(k) Premarket Notification

April 14, 2014 ORA Implant Abutment System

	ScrewPlant
Minimatic/Stryker	3.3 External Hex Cylinder, 3.75 External Hex Screw, 4.0 External Hex Cylinder, 4.0 External Hex Screw, 4.75 External Hex Screw, 5.0 External Hex Cylinder
Straumann	Straumann Bone Level RC, Blue Sky Bio Square Taper RC
Straumann	Straumann Bone Level NC, Blue Sky Bio Square Taper NC
Ankylos	Ankylos
Nobel Biocare	Nobel Replace WP, Nobel Replace Select WP, NobelSpeedy Replace WP, Implant Direct 5.0 RePlant, BlueSky Bio 5.0 Trilobe
Nobel Biocare	Nobel Conical Connection RP
Nobel Biocare	Nobel Conical Connection NP, Blue Sky Bio Max
Astra Dental	Astra 4.5 / 5.0, Blue Sky Bio Conus 12 4.5 / 5.0
Astra Dental	Astra 3.5 / 4.0, Blue Sky Bio Conus 12 3.5 / 4.0
Zimmer Dental	Zimmer TSV 5.7mm, Implant Direct Legacy 5.7, BioHorizon 5.7

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGNEEDED)					
Concurrence of (	CDRH, Office	of Device Evaluation (ODE)			
Prescription Use X (Part 21 CFR 801 Subparts D)	AND/OR	Over-the -Counter Use (21 CFR 807 Subpart D)			

Sheena A. Green - S 2014.04.16 11:34:03 - 04'00'



23 Frank Mossberg Drive · Attleboro, MA 02703 http://www.sterngold.com

Tel: (508) 226-5660 Cust. Serv: (800) 243-9942

Fax: (508) 226-5473 Toll Free Fax: (800) 531-2685

K133791

Alloys Attachments Implants Restorative Systems

### **ECOPY COVER LETTER**

FDA CDRH DMC DEC 1 3 2013

December 12, 2013

Received

U.S. Food and Drug Administration Center for Devices and Radiological Health Document Mail Center-W066-0609 10903 New Hampshire Avenue Silver Spring, MD 20993-0002

RE: Abbreviated 510(k) Premarket Notification ORA Implant Abutment System

I am providing one eCopy on CD containing seventeen (17) PDF files numbered as 001 - 017.

The eCopy is an exact duplicate of the paper copy being submitted.

Should you have any questions, please contact me at 508.226.5660 ext: 1206.

Sincerely,

Maria Rao Director of Regulatory Affairs Sterngold Dental LLC

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118



Tel: (508) 226-5660 Cust. Serv: (800) 243-9942

Fax: (508) 226-5473

Toll Free Fax: (800) 531-2685

23 Frank Mossberg Drive · Attleboro, MA 02703 http://www.sterngold.com

Alloys Attachments Implants Restorative Systems

### **ECOPY COVER LETTER**

December 12, 2013

U.S. Food and Drug Administration Center for Devices and Radiological Health Document Mail Center-W066-0609 10903 New Hampshire Avenue Silver Spring, MD 20993-0002

RE: Abbreviated 510(k) Premarket Notification ORA Implant Abutment System

I am providing one eCopy on CD containing seventeen (17) PDF files numbered as 001 - 017.

The eCopy is an exact duplicate of the paper copy being submitted.

Should you have any questions, please contact me at 508.226.5660 ext: 1206.

Sincerely,

Maria Rao Director of Regulatory Affairs

Sterngold Dental LLC

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET    Date of Submission	Records p	DEPARTMENT OF HEALTH A	D HÜMAN SERVIC		eleased by CD	RH on 09 Form Appro	oval	
Date of Submission   December   FDA Submission   Document Number   If Rnown)	CDRH PRE			COVER SH	EET	Expiration [	Date: Dec	cember 31, 2013
SECTION A	Date of Submission	User Fee Payment	ID Number		FDA Submiss			
PMA PMA & HDE Supplement   Corporation Studmission   Regular (186 day)   Corporation PDP   Motor of Completion   Traditional Information   Regular (186 day)   Corporation PDP   Motor of Completion   Traditional PDP   Motor of Completion   Traditional Information   Regular (186 day)   R	11/26/2013	(b)(4)						
Original Submission	SECTION A		TYPE OF S	UBMISSION				
Permarker Report	PMA	PMA & HDE Supplement	PI	OP	510(k)		Requ	est for Feedback
Panel Track (PMA Only)   Amendment   Special   Submission   Submissi	Original Submission	Regular (180 day)	Original P	DP	Original Submission:		Pre-	Submission
Application   Applicable   Additional Information   Additional Inform	Premarket Report	Special	Notice of	Completion	Traditional		Info	rmational Meeting
Substitution Name   Sterngold Detail, LLC   Division Name   (If applicable)   Steet Address   Steet Address   Steet Address   Steet Address   Steep Address		1 17	Amendme	ent to PDP	La - pro-			•
Additional Information   Additional Informat	=	- <del>                                   </del>			Abbreviated (Complete section I. Page 5)			
Licensing Agreement	i i i i i i i i i i i i i i i i i i i	-	·					-
Amendment DRA & Holfs Supplement   Other (specify):   Other (specify):		lanear T			Third Party	.		
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Original Submission	IDE		Class II Exem	ption Petition	Class III Desig	nation	Oth	er Submission
Amendment Supplement Supplement Report Amendment Supplement Report Amendment Report R	Original Submission	Original Submission	Original S	ubmission			513	B(g)
Supplement   Supplement   Report   Re	Amendment	Amendment	Additional	Information		1		
Have you used or cited Standards in your submission?	Supplement	Supplement					(ae	scripe submission):
Have you used or cited Standards in your submission?		2000						
SECTION B Company / Institution Name Sterngold Dental, LLC Division Name (if applicable) Streed Address 23 Frank Mostberg Drive Contact Title Director of Quality & Regulatory Affairs SECTION C Company / Institution Name (if applicable)  APPLICATION CORRESPONDENT (e.g., consultant, if different from above) Company / Institution Name (if applicable)  Phone Number (including area code) 508-226-7528  City State / Province MA  2719/Postal Code Quntry U.S.  Contact Title Director of Quality & Regulatory Affairs  SECTION C Company / Institution Name Stemgold Dental, LLC Division Name (if applicable)  Phone Number (including area code) 508-256-5660  Street Address FAX Number (including area code) 508-256-5660  Street Address FAX Number (including area code) 508-256-5660  Street Address FAX Number (including area code) 508-256-5660  Street Address City State / Province MA  2719 Code Country U.S.  Contact Title Contact E-mail Address  FAX Number (including area code) 508-226-7528  City Attleboro Contact Title Contact E-mail Address  Contact Title Contact E-mail Address		Report Amendment						
Establishment Registration Number (if known)   Sterngold Dental, LLC   2921595	Have you used or cited Stand	dards in your submission?	Yes No	(If Yes,	please complete Se	ction I, Page	5)	
Sterngold Dental, LLC  Division Name (if applicable)  Phone Number (including area code) 508-556-5660  Street Address  FAX Number (including area code) 508-256-7528  State / Province Attleboro  MA  State / Province Maria Rao  Contact Title Director of Quality & Regulatory Affairs  SECTION C  APPLICATION CORRESPONDENT (e.g., consultant, if different from above)  Company / Institution Name Sterngold Dental, LLC  Division Name (if applicable)  Phone Number (including area code) 508-556-5660  Street Address 23 Frank Mossberg Drive  City Attleboro  State / Province APPLICATION CORRESPONDENT (e.g., consultant, if different from above)  Sterngold Dental, LLC  Division Name (if applicable)  Sterngold Dental, Consultant, Cons	SECTION B	SUBM	ITTER, APPLI	CANT OR SP	ONSOR			
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Contact Name  Maria Rao  Contact Title  Contact E-mail Address	Attleboro					02703		U.S.
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Contact Title Contact E-mail Address								
	IVIAITA KAO	Mana Kau						
	Contact Title			Contact E-mail A	Address			
		ry Affairs		maria.rao@sterngold.com				

Page 1 of 5 Pages

FORM FDA 3514 (1/13)

	ASON FOR APPLICATION - PMA, PDP, OR	
New Device Withdrawal Additional or Expanded Indications Request for Extension Post-approval Study Protocol Request for Applicant Hold Request for Removal of Applicant Hold Request to Remove or Add Manufacturing Site  Process change: Manufacturing Packaging Sterilization Other (specify below)  Response to FDA correspondence:	Change in design, component, or specification:  Software / Hardware Color Additive Material Specifications Other (specify below)  Labeling change: Indications Instructions Performance Characteristics Shelf Life Trade Name Other (specify below)	Location change:  Manufacturer Sterilizer Packager  Report Submission: Annual or Periodic Post-approval Study Adverse Reaction Device Defect Amendment  Change in Ownership Change in Correspondent Change of Applicant Address
Other Reason (specify):		
SECTION D2  New Device New Indication Addition of Institution Expansion / Extension of Study IRB Certification Termination of Study Withdrawal of Application Unanticipated Adverse Effect Notification of Emergency Use Compassionate Use Request Treatment IDE Continued Access	REASON FOR APPLICATION - IDE  Change in:	Response to FDA Letter Concerning:  Conditional Approval Deemed Approved Deficient Final Report Deficient Progress Report Deficient Investigator Report Disapproval Request Extension of Time to Respond to FDA Request Meeting Request Hearing
Other Reason (specify):  SECTION D3	REASON FOR SUBMISSION - 510(k)	
New Device	Additional or Expanded Indications	Change in Technology
Other Reason (specify):		
FORM FDA 3514 (1/13)		Page 2 of 5 Pages

-	ECTION E oduct codes of devices to	whic			NAL INFORMATION	ON ON 5	10(K)	SUBI	VIIS	AOI8	Summary of	or statemen	t concerning,
1	DZE	2	NHA		3		4				safety and eff	ectiveness i	nformation
5		6			7		8				1	(k) summar (k) statemer	
In	ormation on devices to wh	ich s	substantial equivalend	e is	claimed (if known)								
	510(k) i	Vum	ber		Trade or Propr	ietary or M	odel N	ame			Ma	nufacturer	
1	K900099			1	The O-Ring System -	ORS				1	Attachments Internat	ional, Inc.	
								and the state of			<u>. 1900 - National de la company de particular de la company de la compa</u>		
2	K130183			2	SFI Bar Abutments					2	Sterngold Dental, LL	.C	
3				3						3			
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	Trade or Proprietary or M	ode	Name for This Devic	e		was			Mod	del Nu	umber		
	Trade or Proprietary or M	ode	Name for This Device	e					Mod	del Nu	umber		
1	ORA 0.4MM [S]							1	904	264			
2	ORA 1.0MM [S]							2	904	265			<u></u>
3	ORA 2.0MM [S]							3	904	266			
4	ORA 3.0MM [S]							4	904	267			
5	ORA 4.0MM [S]							5	904	268			
	A document numbers of all	<u> </u>	or related submissions	<del>_``</del> _	gardless of outcome)	T .							
1		2		3		4				5		6	
7		3		9		10				11		12	
Dai	a Included in Submission		Laboratory Te		-	Animal Tria			DWW.W711-440		Human Trials		
	CTION G duct Code   C.F.		PRODUCT CL ection (if applicable)	AS.	SIFICATION - APP	PLICATION		ALL evice C		PLIC	CATIONS		
	2.3630 C.P.1	r. 5	еспон (п аррпсавте)						ass I		Class II		
	ssification Panel		<del>,</del>	oorat maran				Cla	ass III	l	Unclassified		
Th	cations <i>(from labeling)</i> e ORA Implant Abutment Sentulous patients to restore								able d	ental	prostheses in the treat	tment of par	tially or totally

Page 3 of 5 Pages

FORM FDA 3514 (1/13)

Recor	as processed under FC	IIA Request # 2	FDA Document Number (if kr.	nown)	KH 011 U9-U0-Z	V-10
Note: Submission of the in need to submit device esta	nformation entered in Section H d ablishment registration.	loes not affect the		,		
SECTION H	MANUFACTURING /	PACKAGING / S	I TERILIZATION SITES RE	LATIN	G TO A SUBMIS:	SION
Original	Facility Establishment Identifier	(FEI) Number	Manufacturer	C	ontract Sterilizer	
Add Delete	10023675		Contract Manufacturer	R	epackager / Relabele	er .
Company / Institution Nam	ne		Establishment Registration N	umber		
Serngold Dental, LLC			2921595			
And the second of the second o	(-)	<u> </u>	Phone Number (including are	o codo)		
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23 Frank Mossberg Drive						
City			State / Province		ZIP Code	Country
Attleboro			MA		02703	U.S.
Contact Name		Contact Title			Contact E-mail Addr	ress
Maria Rao		Director of QA & R	egulatory Affairs		maria.rao@sterngo	
Waria Nao		Director of QA & N	egulatory remains		mara.rao (e) sterrigo	-
Bandina (a seminara de seminar	Facility Establishment Identifier (	(FFI) Number				
Original	Tability Establishment radiation (	(1 21) 110,1100.	Manufacturer	L	ontract Sterilizer	
Add Delete			Contract Manufacturer		epackager / Relabele	r ·
Company / Institution Nam	e		Establishment Registration No	umber		
Division Name (if applicabl	e)	-	Phone Number (including are	a code)		
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City			State / Province		ZIP Code	Country
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Original	Facility Establishment Identifier (	FEI) Number	Manufacturer	Co	ontract Sterilizer	
Add Delete			Contract Manufacturer	Re	packager / Relabele	r
Company / Institution Name	9	· · · · · · · · · · · · · · · · · · ·	Establishment Registration Nu	umber		
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Street Address			FAX Number (including area of	code)		
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Contact Name		Contact Title	and Williams and the control of the	g at each	Contact E-mail Addr	ess
FORM FDA 3514 (1/13			Add	Contin	uation Page Pa	age 4 of 5 Pages

FORM FDA 3514 (1/13)

Records processed under FOIA Request # 2016-1128: Released by CDRH on 09-06-2016

UTILIZATION OF STANDARDS SECTIONI

Note: Complete this section if your application or submission cites standards or includes a "Declaration of Conformity to a Recognized Standard" statement

	Stand	lard" statement.							
ľ		Standards No.	Standards	Standards Title	Version	Date			
	4	F136-12a	Organization ASTM	Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant	English	01/01/2012			
	1			Applications					
		Standards No.	Standards	Standards Title	Version	Date			
	2	15223-1: 2012	Organization AAMI/ANSI/ISO	Medical devices - Symbols to be used with medical device labels, labelling, and information to be supplied - Part 1: General requirements	English	01/01/2012			
		Standards No.	Standards	Standards Title	Version	Date			
			Organization						
		10993-1:2009	AAMI/ANSI/ISO	Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process.	English				
	3			testing within a risk management process.		01/01/2009			
Γ		Standards No.	Standards	Standards Title	Version	Date			
		10993-5: 2009	Organization	Biological evaluation of medical devices Part 5: Tests for In Vitro	English				
			AAMI/ANŠI/ISO	cytotoxicity		01/01/2009			
	4					0170172007			
						,			
$\mid$		Standards No.	Standards Organization	Standards Title	Version	Date			
		F2459-12	<u> </u>	Standard Test Method for Extracting Residue from Metallic Medical	English				
	5		ASTM	Components and Quantifying via Gravimetric Analysis.		01/01/2012			
		Standards No.	Ctondards	Standards Title	Version	Date			
			Standards Organization			Date			
		17665-1:2006	ISO	Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a	English				
	6			sterilization process for medical devices.		01/01/2006			
t		Standards No.	Standards	Standards Title	Version	Date			
		17665-2: 2009	Organization ISO	Sterilization of health care products - Moist heat - Part 2: Guidance on					
		17005-2. 2007	150	the application of ISO 17665-1.		01/01/2000			
	7				English	01/01/2009			
				*	-				
	- 1								

Please include any additional standards to be cited on a separate page.

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

### \*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF ADDRESS BELOW.\*

The burden time for this collection of information is estimated to average 0.5 hour 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 1350 Piccard Drive, Room 400 Rockville, MD 20850

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information unless it displays a currently valid OMB control number.

Page 5 of 5 Pages

## Addendum to Product Information - Section F of Form FDA 3514 Records processed under FOIA Request # 2016-1128; Released by CDRH on 09-06-2016

Trade or Proprietary or Model Name of Device	Model Number
ORA 1.25MM [A]	904335
ORA 2.0MM [A]	904336
ORA 3.0MM [A]	904337
ORA 4.0MM [A]	904338
ORA 5.0MM [A]	904339
ORA 1.0MM [B]	904340
ORA 2.0MM [B]	904341
ORA 3.0MM [B]	904342
ORA 4.0MM [B]	904343
ORA 5.0MM [B]	904344
ORA 1.0MM [C]	904345
ORA 2.0MM [C]	904346
ORA 3.0MM [C]	904347
ORA 4.0MM [C]	904348
ORA 5.0MM [C]	904349
ORA 1.0MM [T]	904374
ORA 2.0MM [T]	904375
ORA 3.0MM [T]	904376
ORA 4.0MM [T]	904377
ORA 5.0MM [T]	904378
ORA 1.0MM [X]	904390
ORA 2.0MM [X]	904391
ORA 3.0MM [X]	904392
ORA 4.0MM [X]	904393
ORA 5.0MM [X]	904394
ORA 1.0MM [Z]	904464
ORA 2.0MM [Z]	904465
ORA 3.0MM [Z]	904466
ORA 4.0MM [Z]	904467
ORA 5.0MM [Z]	904468
ORA 1.0MM [BD]	904469
ORA 2.0MM [BD]	904470
ORA 3.0MM [BD]	904471
ORA 4.0MM [BD]	904472
ORA 5.0MM [BD]	904474
ORA 1.0MM [BE]	904550
ORA 2.0MM [BE]	904551
ORA 3.0MM [BE]	904552
ORA 4.0MM [BE]	904553
ORA 5.0MM [BE]	904554
ORA 1.0MM [AE]	904555
ORA 2.0MM [AE]	904556
ORA 3.0MM [AE]	904557
ORA 4.0MM [AE]	904558
ORA 5.0MM [AE]	904559

### Addendum to Product Information - Section F of Form FDA 3514

Records processed under FOIA Request # 2016-1128; Released by CDRH on 09-06-2016

Trade or Proprietary or Model Name of Device	Model Number
ORA 1.0MM [AN]	904670
ORA 2.0MM [AN]	904671
ORA 3.0MM [AN]	904672
ORA 4.0MM [AN]	904673
ORA 5.0MM [AN]	904674
ORA 1.0MM [AP]	904675
ORA 2.0MM [AP]	904676
ORA 3.0MM [AP]	904677
ORA 4.0MM [AP]	904678
ORA 5.0MM [AP]	904679
ORA 1.0MM [AY]	904680
ORA 2.0MM [AY]	904681
ORA 3.0MM [AY]	904682
ORA 4.0MM [AY]	904683
ORA 5.0MM [AY]	904684
ORA 1.0MM [AJ]	904685
ORA 2.0MM [AJ]	904686
ORA 3.0MM [AJ]	904687
ORA 4.0MM [AJ]	904688
ORA 5.0MM [AJ]	904689
ORA 1.0MM [AK]	904690
ORA 2.0MM [AK]	904691
ORA 3.0MM [AK]	904692
ORA 4.0MM [AK]	904693
ORA 5.0MM [AK]	904694
ORA 1.0MM [BF]	904695
ORA 2.0MM [BF]	904696
ORA 3.0MM [BF]	904697
ORA 4.0MM [BF]	904698
ORA 5.0MM [BF]	904699

### Records processed under FOIA Request # 2016-1128; Released by CDRH on 09-06-2016

	Total Approva. GMO NO. 0710-0711 Expiration Date: April 70, 2010. See Institutions for ONE Statemen
DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET	PAYMENT IDENTIFICATION NUMBER: (b)(4) Write the Payment Identification number on your check.
A completed cover sheet must accompany each original application courier, please include a copy of this completed form with paymen http://www.fda.gov/oc/mdufma/coversheet.html	n or supplement subject to fees. If payment is sent by U.S. mail or t. Payment and mailing instructions can be found at:
COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)	CONTACT NAME     Maria Rao     1.1 E-MAIL ADDRESS
STERNGOLD DENTAL LLC 23 FRANK MOSSBERG DR.	maria.rao@sterngold.com 2.2 TELEPHONE NUMBER (include Area code)
ATTLEBORO MA 02703 US	508-226-5660 1206 2.3 FACSIMILE (FAX) NUMBER (Include Area code)
1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) *****2662	508-226-5473
TYPE OF PREMARKET APPLICATION (Select one of the follow descriptions at the following web site:     http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance	wing in each column; if you are unsure, please refer to the application
Select an application type:	3.1 Select a center
[X] Premarket notification(510(k)); except for third party	[X] CDRH
[] 513(g) Request for Information	[]CBER
[] Biologics License Application (BLA)	3.2 Select one of the types below
[] Premarket Approval Application (PMA)	[X] Original Application
[] Modular PNiA	Supplement Types:
**	
[] Product Development Protocol (PDP)	[] Efficacy (BLA)
[] Premarket Report (PMR)	[] Panel Track (PMA, PMR, PDP)
[] 30-Day Notice	[] Real-Time (PMA, PMR, PDP)
	[] 180-day (PMA, PMR, PDP)
ADENOMA CHANGE COMPANIES C	
<ol> <li>ARE YOU A SMALL BUSINESS? (See the instructions for more [X] YES, I meet the small business criteria and have submitted the qualifying documents to FDA</li> </ol>	required NO, I am not a small business
4.1 If Yes, please enter your Small Business Decision Number: S	BD138617
5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMP THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABI [X] YES (All of our establishments have registered and paid the fee	ANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE LISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?  To refine the control of t
30 days of FDA's approval/clearance of this device.)	paid all fees due to FDA. This submission will not be processed; see
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ additional information)	HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm for
IS THIS PREMARKET APPLICATION COVERED BY ANY OF TAPPLICABLE EXCEPTION.    This application is the first PMA submitted by a qualified small but a process of the proces	
including any affiliates	conditions of use for a pediatric population
[] This biologics application is submitted under section 351 of the F Health Service Act for a product licensed for further manufacturing u	WORLD appropriate antibuter a device that is not to be distributed.
7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION (subject to the fee that applies for an original premarket approval applied [] YES [X] NO	OF USE FOR ANY ADULT POPULATION? (If so, the application is
instructions, searching existing data sources, gathering and maintain	to average 18 minutes per response, including the time for reviewing ning the data needed, and completing and reviewing the collection of other aspect of this collection of information, including suggestions for
Department of Health and Human Services, Food and Drug Adminis Floor Rockville, MD 20850 [Please do NOT return this form to the above address, except as it p	
8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREM	
	20 00p 2010

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### Abbreviated 510(k) Premarket Notification

### **ORA Implant Abutment System**

**Sterngold Dental LLC** 23 Frank Mossberg Drive Attleboro, MA 02703

December 12, 2013

### ORA Implant Abutment System Abbreviated 510(k) Premarket Notification

### TABLE OF CONTENTS

Section 1 510(k) Premarket Notification Screening Checklist	1.1 – 1.3
Section 2 Indications for Use Statement	2.1 – 2.2
Section 3 Cover Letter	3.1 – 3.2
Section 4 Attachment A - Requirements per 21 CFR 807.87	4.1 – 4.3
Section 5 Attachment B - Device Description	5.1 – 5.6
Section 6 Attachment B.1 - Device Drawings	6.1 – 6.11
Section 7 Attachment C - Substantial Equivalence	7.1 – 7.6
Section 8 Attachment D - Conformity with FDA Guidance Documents	8.1 - 8.21
Section 9 Attachment E - Proposed Device Draft Labeling	9.1 – 9.5
Section 10 Attachment F - Packaging, Sterilization and Pyrogenicity	10.1 - 10.3
Section 11 Attachment G - Truthful and Accurate Statement	11.1 - 11.2
Section 12 Attachment H - Instructions for Use	12.1 – 12.4
Section 13 Attachment I - 510(k) Summary	

# 510(k) PREMARKET NOTIFICATION SCREENING CHECKLIST

**SECTION 1** 

Premarket Notification Screening Checklist (Abbreviated 510(k))

(Abbreviated 5		Net Dresent	I Leastier/
	Yes/ Present	Not Present/ Not Required	Location/ Comments
Cover Letter clearly identifies the type of	X		Cover Letter
510(k) submission as: Abbreviated		t en managen deur tieten gegenner te zu en set met mente met en te tre te met er te mit et de met en de met en	and the second course of the second s
Section 1: Required Elements for All Types			and the second s
of 510(k) Submissions			
Elements listed on page 3-2 of the Premarket			
Notification [510(k)] Manual			
Date of application	X		Cover Letter
Applicant's and/or manufacturer's name and	Х		Attachment A
street address			
<ul> <li>Contact person (if different from applicant)</li> </ul>	X		Attachment A
<ul> <li>Telephone and FAX numbers of applicant or</li> </ul>	X		Attachment A
contact			
Signature of the applicant	X		Cover Letter
<ul> <li>Addresses of manufacturing and sterilization</li> </ul>	Х		Attachment A
site(s) as appropriate			
Table of Contents	Х	* + :	Table of
Turkbal and Annuals Olstonaut	V		Contents
Truthful and Accurate Statement	X		Attachment G
Device's Trade Name, Device's Classification	Х		Attachment A
name and Establishment Registration Number  Device's Classification Regulation Number and	X		Attachment A
Status (Class I, Class II, Class III or Unclassified)	^		Allaciiiieiil A
Proposed Labeling including the information listed	Х		Attachment E
on page 3-4 of the Premarket Notification [510(k)]	^		Audomnon
Manual			
Statement of Indications for Use that is on a	Х		Indications for
separate page in the premarket submission			Use
			Statement
Substantial Equivalence Comparison, including	X		Attachment C
comparisons of the new device with the predicate			
in areas that are listed on page 3-4 of the			
Premarket Notification [510(k)] Manual			And I di
510(k) Summary or 510(k) Statement	XX		Attachment I
Description of device (or modification of the	X		Attachment B
device) including diagrams, engineering drawings,			
photographs or service manuals  Identification of legally marketed predicate device*	V		Attachment C
Compliance with performance standards * [See	X		Attachment A
Section 514 of the Act and 21 CFR 807.87(d)]	^		AuacimentA
Class III Certification and Summary		Х	
Financial Certification or Disclosure Statement for	X		Not required -
510(k)'s notifications with a clinical study * [See 21			no clinical
CFR 807.87(i)]	-		study
510(k) Kit Certification ***		Χ	Not a kit

	Yes/ Present	Not Present/ Not Required	Location/ Comments
Section 2: Required Elements for a SPECIAL 510(k)		N/A	Not applicable - not a Special 510(k)
Section 3: Required Elements for an ABBREVIATED 510(k) *			
For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type. (If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.)	X		Attachment D
For a submission, which relies on a recognized standard, a declaration of conformity [See Required elements for a Declaration of Conformity]	Х		Attachment D
For a submission, which relies on a recognized standard without a declaration of conformity, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		Х	Attachment D
For a submission, which relies on a non- recognized standard that has been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		Х	Attachment D
For a submission, which relies on a non-recognized standard that has <u>not</u> been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device <u>and</u> any additional information requested by the reviewer in order to determine substantial equivalence.		X	Attachment D
Any additional information, which is not covered by the guidance document, special control, recognized standard, in order to determine substantial equivalence.	Х		Attachment C
<ul> <li>List of all guidance documents, special controls, recognized standards and/or non-recognized standards, which were noted by the sponsor.</li> </ul>	X		Attachment D

### INDICATIONS FOR USE STATEMENT

### **SECTION 2**

5 IU(K) Number (I	r known):		
Device Name: C	)RA Implant Abi	utment System	
	estantisting ordered in American Stantisting Stantisti	and a property of the second s	
Indications for L	Jse:		
and/or retain remov	vable dental pros to restore chewi	theses in the tr	or use with dental implants to support reatment of partially or totally the abutment screws directly into
(PLEASE DO NO PAGE IF NEEDE		OW THIS LIN	NE - CONTINUE ON ANOTHER
Concu	irrence of CDR	H, Office of [	Device Evaluation (ODE)
Prescription Use _ (Part 21 CFR 801		AND/OR	Over-the -Counter Use (21 CFR 807 Subpart D)

### **COVER LETTER**

### **SECTION 3**

December 12, 2013

U.S. Food and Drug Administration Center for Devices and Radiological Health Document Mail Center-W066-0609 10903 New Hampshire Avenue Silver Spring, MD 20993-0002

RE: Abbreviated 510(k) Premarket Notification ORA Implant Abutment System

This Premarket Notification is an **Abbreviated 510(k)** as defined in FDA's March 20, 1998 Final Guidance entitled <u>The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications."</u>

The ORA Implant Abutments described in this submission is appropriate for an Abbreviated 510(k) because the proposed product was developed in accordance with and is in compliance with the following relevant FDA guidance documents and/or recognized consensus standards:

 Guidance for Industry and FDA Staff Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments. (Draft FDA Guidance; distributed for comment May 12, 2004)

Sterngold hereby requests that the Food and Drug Administration (FDA) hold confidential the information of their intent to seek 510(k) clearance for these devices. To the best of our knowledge, neither we nor anyone else has disclosed through advertising to physicians, scientists, market analysts, exporters, or other individuals, or through any other manner, our intent to seek 510(k) clearance for these devices in the United States, except employees of or consultants to our company and pursuant only to appropriate contractual arrangements with appropriate safeguards for secrecy.

This 510(k) Premarket Notification is submitted in two paper copies and one E-Copy. Should you have any questions, please contact me at 508.226.5660 ext: 1206.

Sincerely,

Maria Rao

Director of Regulatory Affairs

Sterngold Dental LLC

### **ATTACHMENT A**

### **REQUIREMENTS PER 21 CFR 807.87**

**SECTION 4** 

### **REQUIREMENTS PER 21 CFR 807.87**

### I. CLASSIFICATION NAME / PRODUCT CODE

Endosseous Dental Implant Abutment / NHA

### II. REGULATION NUMBER

21CFR 872.3630

#### III. DEVICE TRADE NAMES

**ORA Implant Abutment System** 

### IV. COMMON OR USUAL NAME

Dental Implant Abutment

### V. 510(k) SPONSOR & OWNER/OPERATOR

Sterngold Dental, LLC 23 Frank Mossberg Drive Attleboro, MA 02703 FDA Registration #2921595

### VI. MANUFACTURING & STERILIZATION SITES

Manufacturing: Sterngold Dental, LLC 23 Frank Mossberg Drive Attleboro, MA 02703 FDA Registration #2921595

### VII. CONTACT PERSONS/AUTHORIZED REPRESENTATIVES

The authorized representative of Sterngold for purposes of interacting and corresponding with FDA on all matters relating to this current 510(k) Premarket Notification is as follows:

Sterilization: N/A

Maria Rao

Director of Quality & Regulatory Affairs

Sterngold Dental, LLC

P. 508.226.5660 ext: 1206

F. 508.226.7528

E-mail: maria.rao@sterngold.com

### VIII. CLASSIFICATION

According to Section 513 of the Federal Food, Drug and Cosmetic Act, the products described in this submission are presently classified as Class II medical devices. Sterngold intends to comply with all regulatory controls appropriate for Class II medical devices.

#### IX. PERFORMANCE STANDARDS

Final Performance Standards as described in Section 514 of the Federal Food, Drug and Cosmetic Act have not been established for the device described in this submission.

### X. DEVICE PANEL

**Dental Products** 

#### XI. LABELING

Labeling for the proposed devices is contained in Attachment E.

### XII. 510(k) SUMMARY

A summary of the safety and effectiveness information contained within this Premarket Notification is contained in **Attachment J**.

#### XIII. POSTMARKETING SURVEILLANCE:

It is the understanding of Sterngold that FDA does not presently require the submission of postmarketing surveillance plans for this type of device, and that manufacturers will be notified when such requirements become applicable.

#### XIV. CLASS III SUMMARY & CERTIFICATION

Not applicable.

### ATTACHMENT B

### **DEVICE DESCRIPTION**

**SECTION 5** 

### **DEVICE DESCRIPTION**

This Abbreviated 510(k) Premarket Notification seeks clearance for the ORA Implant Abutments.

The ORA Implant Abutment System is a precision machined ball shaped abutment that connects a compatible dental implant system with a removable partial or complete overdenture. The implant abutment is screwed into the dental implant. Connection to and retention of a denture is provided by a rubber o-ring, which may or may not be held within a metal housing. There are two color o-rings, a red processing o-ring and a white final o-ring. Connection and retention may also be provided by a plastic keeper that is processed into the denture.

The bottom portion of the abutment (cuff area to end of threads) is an exact replica of the SFI Implant Abutments previously cleared by K130183.

The ORA Implant Abutment System is available in sixteen different platforms and each platform is compatible with one or more implant types. Table 1 demonstrates implant/abutment compatibility. The difference between each platform is the internal connection with the specific implant. This connection has been previously cleared by K130183 – SFI Abutments.

Implant Brand	Model
Straumann [BD]	Straumann Bone Level RC, Blue Sky Bio Square Taper RC
Straumann [BE]	Straumann Bone Level NC, Blue Sky Bio Square Taper NC
Ankylos [AE]	Ankylos
Nobel Biocare	Nobel Replace WP, Nobel Replace Select WP, Nobel Speedy Replace WP, Implant Direct 5.0
[AN]	RePlant, BlueSky Bio 5.0 Trilobe
Nobel Biocare	Nobel Conical Connection RP, Blue Sky Bio Max
[AP]	
Nobel Biocare	Nobel Conical Connection NP
[AY]	
Astra Dental [AJ]	Astra 4.5 / 5.0, Blue Sky Bio Conus 12 4.5 / 5.0
Astra Dental [AK]	Astra 3.5 / 4.0, Blue Sky Bio Conus 12 3.5 / 4.0
Zimmer Dental	Zimmer TSV 5.7mm, Implant Direct Legacy 5.7, BioHorizon 5.7
[BF]	
Nobel Biocare	3.3 Fixture, 3.75 Fixture, 4.0 Fixture, 5.0 Fixture (Old Version), 3.75 MkII Self-tapping Fixture,
Brånemark System	4.0 MkII Self-tapping Fixture
[A]	
Sterngold-	3.3 Hex Cylinder, 4.0 Hex Cylinder, 3.75 Standard Hex Screw, 3.75 Self-tapping Hex Screw,
ImplaMed [A]	3.75 Self-tapping "SST" Hex Screw, 4.0 Standard Hex Screw, 4.0 Self-tapping Hex Screw, 4.0
	Self-tapping "SST" Hex Screw, 4.0 Self-tapping "SST" Hex Screw, 5.0 RP "SST" Hex Screw,
	3.75 RP Acid Etched, 4.0 RP Acid Etched, 5.0 RP Acid Etched
Sterngold-	4.1 Stern IC (4.8 head), 3.3 Stern IC (4.8 head)
ImplaMed [S]	

,	
Nobel Biocare	3.8 HL Cylinder, 3.8 HL Threaded, 4.5 HL Threaded
(Steri-Oss®) [A]	
Nobel Biocare	3.5 NobelReplace <sup>TM</sup> , Replace <sup>®</sup> Select (NP)
(Steri-Oss®) [Z]	
Nobel Biocare	4.0 NobelReplace Straight, (RP), 4.3Replace®Select&NobelReplace™ (RP)
(Steri-Oss®) [T]	
Keystone	3.75 Restore® Self-tapping Screw, 4.0 Restore® Self-tapping Screw, 3.75 Restore® External
(Lifecore) [A]	Hex Screw, 4.0 Restore® External Hex Screw, 4.0 Restore® External Hex Cylinder, 4.2
(21100010)[11]	Sustain® External Hex Cylinder, 3.75 Sustain® External Hex Screw, 4.0 Sustain® External
	Hex Screw, 4.2 Sustain® External Hex MC Cylinder,
Keystone	Stage-1 <sup>TM</sup> (3.3 and 4.0 fixtures)
(Lifecore) [S]	Sugo 1 (3.5 and 4.0 lixtures)
3i Implant	3.25 External Hex Miniplant®, 3.25 ICE TM Miniplant®, 3.25 OSSEOTITE® Miniplant®, 3.3
, -	Cylinder Miniplant®, 3.3 External Hex Cylinder, 3.75 ICE <sup>TM</sup> Self-tapping, 3.75
Inovations [A]	OSSEOTITE®, 3.75 Self-tapping Threaded, 3.75 Standard Threaded, 4.0 External Hex
	Cylinder, 4.0 ICE TM Self-tapping,
2: Immlant	<u> </u>
3i Implant	TG OSSEOTITE® (4.8 Platform)
Inovations [S]	A A CONTROL A A CO. 1 1 MI 1 1 A A C. E. 4 1 H. C. L. 1 A A CONTROL A
3i Implant	4.0 OSSEOTITE®, 4.0 Standard Threaded, 4.25 External Hex Cylinder, 4.0 OSSEOTITE®
Inovations [X]	Certain TM, 4.0 OSSEOTITE® NTCertain TM, 4.0 OSSEOTITE® CERTAIN PREVAIL, 5.0
	Osseotite® Certain, 5.0 Osseotite® NT Certain, 5.0 Osseotite® Certain Prevai
IMTEC	3.3 Universal Flare Cylinder, 3.75 Universal Self-tapping, 3.75 Universal Self-tapping Coated,
Corporation® [A]	4.0 Spike Cylinder, 4.0 Universal Cylinder
Interpore IMZ [A]	3.3 Hex Cylinder, 3.75 Self-tapping Threaded, 4.0 Hex Cylinder, 4.0 Self-tapping Threaded,
***************************************	4.25 Hex Cylinder
Osstem [A]	4.1 US II, III, II Plus, III Plus
Osstem [S]	SS II, III (4.8 head)
Zimmer Dental[A]	3.5 Bio-Vent® X <sup>TM</sup> , 3.75 Swede-Vent TM Conical Neck CST, 3.75 Swede-Vent TM Standard,
	4.0 Swede-Vent IM Standard, 4.0 Bio-Vent® X IM,
Zimmer Dental [B]	3.25 Micro-Vent® (3.5 head), 3.3 Screw-Vent® (3.5 head), 3.5 Bio-Vent® (3.5 head), 3.7
	Screw-Vent® (3.5 head), 3.75 Screw-Vent® (3.5 head), 4.3 Core-Vent® (3.5 head)
Zimmer Dental [C]	4.25 Micro-Vent® (4.5 head), 4.5 Bio-Vent® (4.5 head), 4.7 Screw-Vent® (4.5 head), 5.3
	Core-Vent® (4.5 head),
Zimmer Dental [S]	3.7 Tapered Swiss Plus TM (4.8 platform), 4.8 Tapered Swiss Plus A.1 Straight
	4.8 Straight Swiss Plus TM
Zimmer	3.75 ThreadLocTM
(Calcitek®,	
Centerpulse) [A]	
Straumann [S]	ITI TE <sup>TM</sup> 3.3 (4.8 head), ITI 3.3 Std & Std Plus (4.8 head), ITI TE <sup>TM</sup> 4.1 (4.8 head), ITI 4.1
La Tal	Std. & Std. Plus (4.8 head), ITI, 4.8 Std. & Std. Plus (4.8 head)
Biolok	4.5 Silhouette Screw, 4.0 Micro-Lok Screw, 4.0 Micro-Lok Cylinder, 3.75 Micro-Lok Screw,
International [A]	3.3 Micro-Lok Cylinder
Bud [A]	3.25 Bud Screwvent, 3.75 Bud Screwvent
INNOVA [A]	4.1 ENDOPORE® External Connection, 4.0 ENTEGRATM External Connection
	3.0 Osteo Standard ST, 3.25 Osteo Standard ST, 3.75 Osteo Standard ST
OIC [A]	5.0 Osteo Standard S1, 5.25 Osteo Standard S1, 5.75 Osteo Standard S1
MIS IMPLANTS	3.3mm Internal Hex, 3.75mm Internal Hex, 4.20mm Internal Hex
[B]	
MIS IMPLANTS	5.0mm Internal Hex
[C]	

BioHorizons® [B]	3.5 Internal, 3.5 Single Stage
BioHorizons® [C]	4.0 Internal, 4.5 Internal, 4.5 Single Stage
Implant Direct [B]	Legacy 3.5mm, 3.7mm ScrewPlant,
Implant Direct C]	Legacy 4.5mm, 4.7mm ScrewPlant
Implant Direct [T]	RePlant <sup>TM</sup> 4.3mm
Implant Direct [Z]	RePlant <sup>TM</sup> 3.5mm
Minimatic/Stryker	3.3 External Hex Cylinder, 3.75 External Hex Screw, 4.0 External Hex Cylinder, 4.0 External
[A]	Hex Screw, 4.75 External Hex Screw, 5.0 External Hex Cylinder

#### **Abutment Insertion**

Choose the abutment with the proper cuff height that fits the existing implant or choose the ORA Abutment that will screw into an SFI Abutment. Screw an abutment into each implant or SFI Abutment. The abutments are tightened to 20 Ncm, using a hex tool which engages the hex at the base of the ball.

The o-ring or keeper is placed onto the ball, any exposed parts of the abutment are blocked out, and the o-ring/keeper is processed into the denture.

### **Material Composition:**

The ORA Implant Abutments are manufactured by the same strict standards as previous Sterngold devices and from the same materials used to manufacture previously devices cleared by K130183.

The material of the implant abutments conform to ASTM F136, Wrought Titanium 6 Aluminum-4 Vanadium ELI Alloy.

The proposed devices do not contain or utilize software.

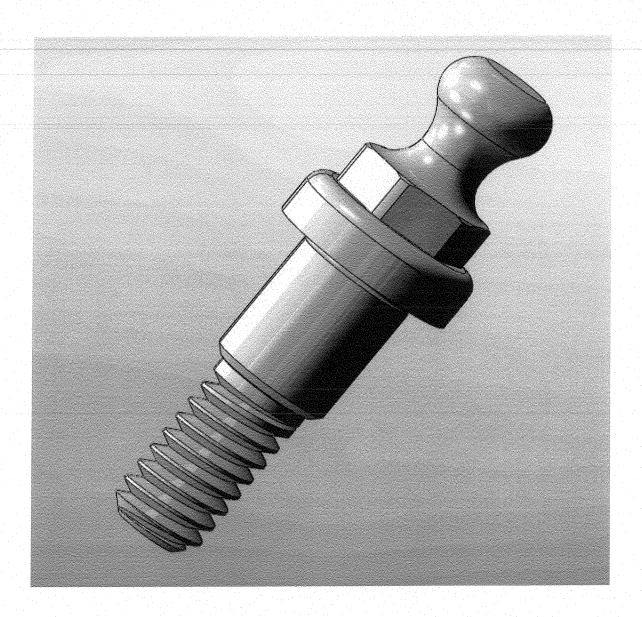
MR Safety: The ORA Implant Abutments are manufactured from a non-ferromagnetic material: 6AL-4V ELI titanium.

Titanium is usually recommended for long term implantable devices because it is safe and completely non-magnetic, non-electrically conductive and non-RF reactive eliminating all of the primary potential threats during an MRI procedure.

The ORA Implant Abutments have not been evaluated for safety and compatibility in the MR environment. The ORA Implant Abutments have not been tested for heating or migration in the MR environment. These statements are included in the Instructions for Use.

Refer to Table C for a 3D photograph of an ORA Abutment.

TABLE C



**Example: ORA Implant Abutment** 

**Device Drawings:** 

Engineering drawings for the proposed ORA Implant Abutments are included in **Attachment B.1**.



### Description



### Indications for Use:

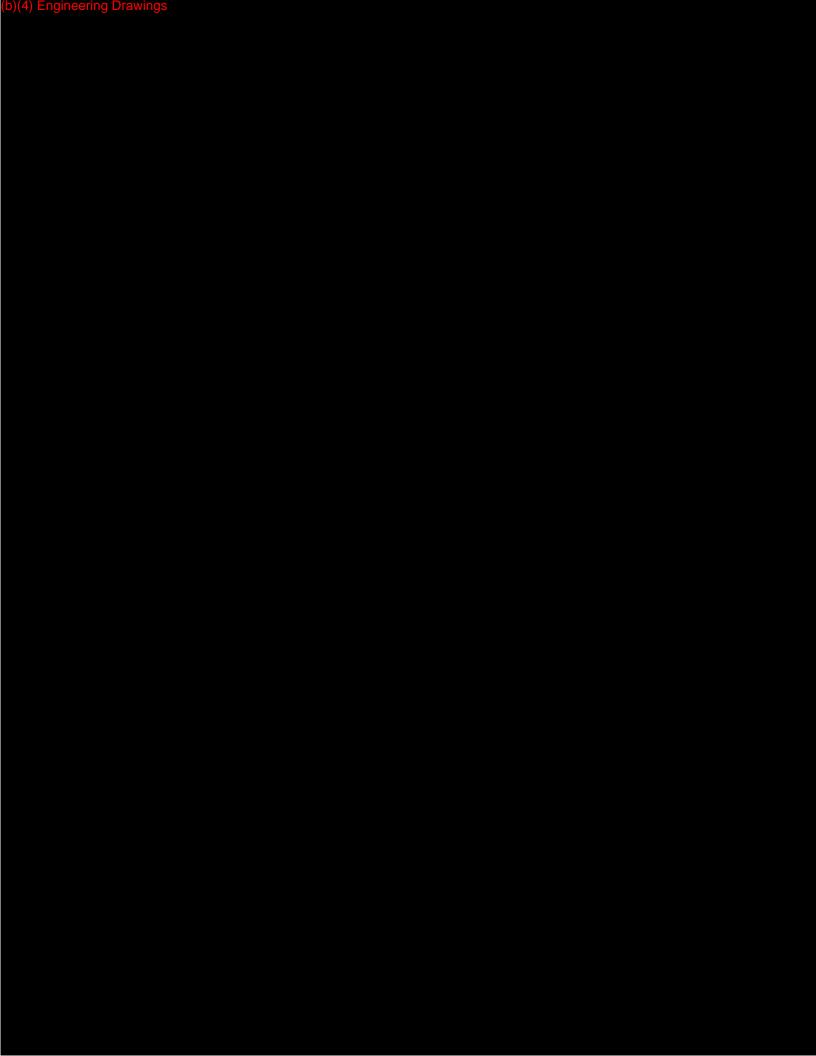
The ORA Implant Abutments are indicated for use with dental implants to support and/or retain removable dental prostheses in the treatment of partially or totally edentulous patients to restore chewing function. The abutment screws directly into endosseous implants.

# **ATTACHMENT B.1**

**DEVICE DRAWINGS** 

#### **DEVICE DRAWINGS**

This Attachment contains the following device drawings for the proposed ORA Implant Abutments.



# ATTACHMENT C SUBSTANTIAL EQUIVALENCE SECTION 7

#### SUBSTANTIAL EQUIVALENCE

The proposed ORA Implant Abutments are substantially equivalent to the currently marketed implant predicate devices. The intended use, basic design, fundamental operating principles and manufacturing procedures are the same as the predicate devices. To ensure compatibility the following process was carried out: The implant abutments were designed, developed, and manufactured according to manufacturer's specifications and controlled procedures. A validation protocol was done in accordance with Design Control requirements per FDA CFR820.30.

K900099 The O-Ring System – ORS

K130183 SFI Bar® Implant Abutments for 7 Platforms

Compatibility was determined by comparing the design features including diameters, lengths, cuff sizes, materials, implant/abutment interface connection, and intended use of the proposed device to predicate devices.

The ORA Abutments are an exact replica of the ORS abutments previously cleared by K900099.

Application testing consisted of (b)(4)

Manufacturer's implants were purchased and (b)(4)

ensure full compatibility.

was performed to

Continuous compatibility with manufacturer's implants indicated on this application and respective abutments will be verified every honths by to ensure compatibility.

The summary of technological characteristics, tolerance analysis, application and functional testing indicate that the device is safe and effective for its intended use and performs as well or better than the predicate devices.

Table A summarizes the substantial equivalence comparison to the predicate devices.

Table A

**Substantial Equivalence Comparison** 

Table A

Attribute	Candidate	Predicate Device	Predicate Device  SFI Implant Abutments Sterngold Dental, LLC  K130183	
	The ORA Implant Abutment Sterngold Dental, LLC	The O-Ring System – ORS Attachments International, Inc. K900099		
Design/Construction	Machined, screw-retained	Machined, screw-retained	Machined, screw-retained	
Anatomical Site	Oral Cavity	Oral Cavity	Oral Cavity	
Device Material	Wrought Titanium-6AL-4 Vanadium ELI Alloy	Wrought Titanium-6AL-4 Vanadium ELI Alloy	Wrought Titanium-6AL-4 Vanadium ELI Alloy	
Indications for Use	Indicated for use with dental implants to support and/or retain removable dental prostheses in the treatment of partially or totally edentulous patients to restore chewing function. The abutment screws directly into endosseous implants.	The ORS Implant Abutments are intended for use with dental implants as a support or attachment for prosthetic restoration. The abutment screws directly into the implant.	The SFI-Bar® Implant Abutments are indicated for use with dental implant bodies/fixtures to support and /or retain removable dental prostheses for partially or totally edentulous patients to restore chewing function.	
Operating Principle/ Basic Design	Abutment Implant connection: Screw fixation	Abutment Implant connection: Screw fixation	Abutment Implant connection: Screw fixation	
	Connecting principle to overdenture: Retentive system	Connecting principle to overdenture: Retentive system	Connecting principle to overdenture: Retentive system	
	Cleaning procedures for patient: Common procedure for oral hygiene	Cleaning procedures for patient: Common procedure for oral hygiene	Cleaning procedures for patient: Common procedure for oral hygiene	
	Patient handling: Common cleaning and insertion of denture	Patient handling: Common cleaning and insertion of denture	Patient handling: Common cleaning and insertion of denture	
Packaging, materials and processes	Produced in a controlled CNC machine process, previously validated Packaging: Pouch Non-sterile	Produced in a controlled CNC machine process, previously validated Packaging: Pouch Non-sterile	Produced in a controlled CNC machine process, previously validated Packaging: Pouch Non-sterile	

# ATTACHMENT D

# **CONFORMITY WITH FDA GUIDANCE DOCUMENT**

#### CONFORMITY WITH FDA GUIDANCE DOCUMENTS

Sterngold certifies that the proposed The ORA Implant Abutments were developed in accordance with and meet the requirements contained in the following consensus standards:

Guidance for Industry and FDA Staff Class II Special Controls Guidance
 Document: Root-form Endosseous Dental Implants and Endosseous Dental
 Implant Abutments. (Draft FDA Guidance; distributed for comment May 12, 2004)

#### Intended Use of the Device (also see Indications for Use Statement):

The ORA Implant Abutments are indicated for use with dental implants to support and/or retain removable dental prostheses in the treatment of partially or totally edentulous patients to restore chewing function. The abutment screws directly into endosseous implants.

#### **Device Description:**

- Design Characteristics See Attachment B
- Material composition—See Attachment B

### Sterilization Information:

See Attachment F

#### **Labeling Information:**

See Attachment E

#### Mechanical Testing:

The applicable FDA guidance requires mechanical testing for implant or abutment designs that are significantly different from those of the predicate devices. As detailed in **Attachment** C, the proposed Stern IC Dental Implant System fall within the range of currently marketed, predicate dental endosseous implant products that have been cleared for marketing through the 510(k) Premarket Notification process. Therefore, mechanical testing is not necessary to establish substantial equivalence for the proposed devices.

#### **Corrosion Testing:**

The applicable FDA guidance requires corrosion testing for implant systems that include components fabricated from dissimilar metals. The proposed ORA Implant Abutments do not contain dissimilar metals; therefore, corrosion testing is not necessary to establish substantial equivalence for the proposed devices.

#### Biocompatibility Testing:

The applicable FDA guidance require biocompatibility testing when a new material is used that has not been identified in a predicate device. The ORA Implant Abutments are manufactured from standard raw materials that have been used extensively in other currently marketed dental implant systems (see **Attachment B**). Therefore, no additional biocompatibility testing is required to establish substantial equivalence.

#### **Animal and Clinical Studies:**

The applicable FDA guidance's request animal and/or clinical studies if the implant diameter is less than 3.0mm, if the length is less than 7mm, and if the angulations of the abutment is greater than 30°, or if the design of the device is significantly different from that of other legally marketed devices. As detailed in **Attachments B** and **C**, the proposed ORA Implant Abutments fall well within the range of currently marketed, predicate devices that has been cleared for marketing through the 510(k) Premarket Notification process. Therefore, animal and/or clinical studies are not necessary to establish substantial equivalence for the proposed devices.

# ATTACHMENT E

# PROPOSED DEVICE DRAFT LABELING

#### PROPOSED DEVICE DRAFT LABELING

This Attachment contains draft labeling for the proposed ORA Implant Abutments

#### Pouch label:

A sample draft label is included on the following pages.

#### Instructions for Use:

Instructions for Use are included on the following pages.

#### **Promotional Literature:**

Promotional literature for the proposed devices is included on the following pages.

#### **Intended Use:**

The ORA Implant Abutments are indicated to be used with dental implants as a prosthetic framework to support and /or retain removable dental prostheses in the treatment of partially or totally edentulous patients to restore chewing function. The abutment screws are intended to secure the bar to the endosseous implants.

The proposed devices are for single use only and are supplied non-sterile.

**MR Safety:** The ORA Implant Abutments are manufactured from a **non-ferromagnetic** material: 6AL-4V ELI titanium.

Titanium is usually recommended for long term implantable devices because it is safe and completely non-magnetic, non-electrically conductive and non-RF reactive eliminating all of the primary potential threats during an MRI procedure.

The ORA Implant Abutments have not been evaluated for safety and compatibility in the MR environment.

The ORA Implant Abutments have not been tested for heating or migration in the MR environment. These statements are included in the Instructions for Use.

The proposed devices do not contain or utilize software.

The labeling on the proposed device was developed in compliance with ANSI/AAMI/ISO 15223-1:2012.

• ISO 15223-1:2012, Medical Devices - Symbols to be used with medical device labels, labeling, and information to be supplied - Part 1: General requirements

The proposed ORA Implant Abutments are listed on Table B.

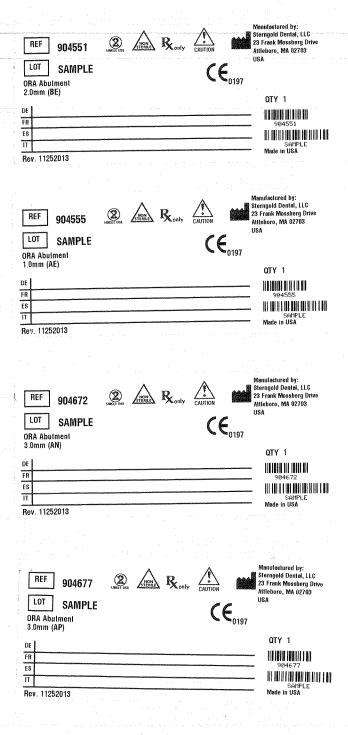
Abbreviated 5.10/kis Previewset Nortilier ation. Request # 2016-1128; Released by CDRRAd mode 2004 ment System

Product No.	Product Description
904264	ORA 0.4MM [S]
904265	ORA 1.0MM [S]
904266	ORA 2.0MM [S]
904267	ORA 3.0MM [S]
904268	ORA 4.0MM [S]
904335	ORA 1.25MM [A]
904336	ORA 2.0MM [A]
904337	ORA 3.0MM [A]
904338	ORA 4.0MM [A]
904339	ORA 5.0MM [A]
904340	ORA 1.0MM [B]
904341	ORA 2.0MM [B]
904342	ORA 3.0MM [B]
904343	ORA 4.0MM [B]
904344	ORA 5.0MM [B]
904345	ORA 1.0MM [C]
904346	ORA 2.0MM [C]
904347	ORA 3.0MM [C]
904348	ORA 4.0MM [C]
904349	ORA 5.0MM [C]
904374	ORA 1.0MM [T]
904375	ORA 2.0MM [T]
904376	ORA 3.0MM [T]
904377	ORA 4.0MM [T]
904378	ORA 5.0MM [T]
904390	ORA 1.0MM [X]
904391	ORA 2.0MM [X]
904392	ORA 3.0MM [X]
904393	ORA 4.0MM [X]
904394	ORA 5.0MM [X]
904464	ORA 1.0MM [Z]
904465	ORA 2.0MM [Z]
904466	ORA 3.0MM [Z]
904467	ORA 4.0MM [Z]
904468	ORA 5.0MM [Z]
904469	ORA 1.0MM [BD]
904470	ORA 2.0MM [BD]
904471	ORA 3.0MM [BD]
904472	ORA 4.0MM [BD]
904474	ORA 5.0MM [BD]
904550	ORA 1.0MM [BE]
904551	ORA 2.0MM [BE]
904552	ORA 3.0MM [BE]
904553	ORA 4.0MM [BE]

Product No.	<b>Product Description</b>
904554	ORA 5.0MM [BE]
904555	ORA 1.0MM [AE]
904556	ORA 2.0MM [AE]
904557	ORA 3.0MM [AE]
904558	ORA 4.0MM [AE]
904559	ORA 5.0MM [AE]
904670	ORA 1.0MM [AN]
904671	ORA 2.0MM [AN]
904672	ORA 3.0MM [AN]
904673	ORA 4.0MM [AN]
904674	ORA 5.0MM [AN]
904675	ORA 1.0MM [AP]
904676	ORA 2.0MM [AP]
904677	ORA 3.0MM [AP]
904678	ORA 4.0MM [AP]
904679	ORA 5.0MM [AP]
904680	ORA 1.0MM [AY]
904681	ORA 2.0MM [AY]
904682	ORA 3.0MM [AY]
904683	ORA 4.0MM [AY]
904684	ORA 5.0MM [AY]
904685	ORA 1.0MM [AJ]
904686	ORA 2.0MM [AJ]
904687	ORA 3.0MM [AJ]
904688	ORA 4.0MM [AJ]
904689	ORA 5.0MM [AJ]
904690	ORA 1.0MM [AK]
904691	ORA 2.0MM [AK]
904692	ORA 3.0MM [AK]
904693	ORA 4.0MM [AK]
904694	ORA 5.0MM [AK]
904695	ORA 1.0MM [BF]
904696	ORA 2.0MM [BF]
904697	ORA 3.0MM [BF]
904698	ORA 4.0MM [BF]
904699	ORA 5.0MM [BF]

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REF 904265 SECTION ROOM CAUTION	23 Frank Mossberg Drive Attleboro, MA 02703
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R	904265
8	SAMPLE
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	Manufactured by:
	<b>國 Sterngold Dental, LLC</b>
REF 904336 SELLINS PROMINE ROUTE	
LOT	4211
LOT SAMPLE	<b>6</b> 0197
ORA Abutment 2.0mm (A)	
	QTY 1
DE FR	994336
ES	
11	SAMPLE Made in USA
Rev. 11252013	little in Cov
	Manufactured by: 題 Sterngold Dental, LLC
REF 904341 SMETTING ROOMY CAUTION	23 Frank Mossberg Brive Attlebore, MA 02703
Local Control	LICA
LOT SAMPLE	<b>6</b> 0197
	0197
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FR	904341
ES IT	SAMPLE
Rev. 11252013	Made in USA
The state of the s	
	Manufactured by:
_	離 Sterngold Dental, LLC
REF 904347 SMEET USS STEARS ROOMS CAUTION	23 Frank Mossberg Drive Attleboro, MA 02703
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LOT SAMPLE	<b>. 6</b> <sub>0197</sub>
ORA Abutment 3.0mm (C)	
	QTY 1
DE	
FR ES	994347
II	SAMPLE Made in USA
Eeu 11252013	Made in USA

REF 904375 Secretors Ronly CAUTION	Manufactured by: Sterngold Dental, LLC 23 Frank Mossberg Drive Attleboro, MA 02703 USA
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FR ES	994375
17	SAMPLE Made in USA
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REF 904392 SMELTING ROOMS ROOMS CAUTION	Manufactured by: Sterngold Dental, LLC 23 Frank Mossberg Drive Attleboro, MA 02703
ORA Abutment CE <sub>0197</sub>	USA
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Rev. 11252013	Made in USA
	Manufactured by: Sterngold Dental, LLC 23 Frank Mossberg Drive
	Attleboro, MA 02703 USA
LOT SAMPLE CE <sub>0197</sub>	
4.0mm (Z)	QTY 1
PR PR	984467
E8    T	
Rev. 11252013	Made in USA
REF COLUZE (2) NOT R Ste	nufactured by: erngold Dental, LLC Frank Mossberg Drive leboro, MA 02703
LOT SAMPLE OBA Abulment  US  OBA Abulment	
ORA Abulment 3.0mm (BD)	
DE	QTY 1
FR FS	994471
FR ES IT	



					and the second second	Manufactured by:
REF 004690	(0)	$\triangle$	D	/!\	000	Sterngold Dental, LLC 23 Frank Mossberg Drive
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						Manufactured by:
	ARIN .	$\wedge$	9"%	A		Sterngold Dental, LLC
REF 904686	2	STERRE	$\mathbf{R}_{\text{only}}$	CAUTION		23 Frank Mossberg Drive
-	30001 031		,	0.101.011		Attleboro, MA 02703 USA
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						SAMPLE Made in USA
Rev. 11252013						made in oon
						Manufactured by:
	·		3736	$\wedge$	لممه	🕻 Sterngold Dental, LLC
REF 904692	(Z)	NON	Ronly	CAUTION		Sterngold Dental, LLC 23 Frank Mossberg Drive
REF 904692	SUNCEFUSE	NON STEMBLE	Ronly			🕻 Sterngold Dental, LLC
304092	SINCIT USE	NON STEARS	Ronly			Sterngold Dental, LLC 23 Frank Mossberg Drive Attleboro, MA 02703
LOT SAMPLE	SINCLE LISE	NON STERME	Ronly		60107 C0107	Sterngold Dental, LLC 23 Frank Mossberg Drive Attleboro, MA 02703
LOT SAMPLE ORA Abutment	SHOUT USE	NO.R STEPHE	Ronly		<b>6</b> 0197	Sterngold Dental, LLC 23 Frank Mossberg Drive Attleboro, MA 02703
LOT SAMPLE	SHOTTESE	NOR STERRE	Ronly		<b>60</b>	Sterngold Dental, LLC 23 Frank Mossberg Drive Attleboro, MA 02703 USA
LOT SAMPLE ORA Abutment 3.0mm (AK)	SHELLFLISE	NO.	Ronly		<b>6</b> 0197	Sterngold Dental, LLC 23 Frank Mossberg Drive Attleboro, MA 02703 USA
LOT SAMPLE ORA Abutment 3.0mm (AK)	SMOLFISS	NO.	Ronly		<b>6</b> 0197	Stempold Dentel, LLC 23 Frank Mossberg Drive Attleboro, MA 02703 USA  OTY 1
LOT SAMPLE ORA Abutment 3.0mm (AK) DE	SNECT USE	NON	Ronly		<b>6</b> 0197	Sterngold Dental, LLC 23 Frank Mossberg Drive Attleboro, MA 02703 USA  OTY 1
LOT SAMPLE ORA Abutment 3.0mm (AK)  DE FR ES	Specifics	NO.	R <sub>only</sub>		<b>6</b> 0197	Sterngold Dental, LLC 23 Frank Mossberg Drive Attleboro, MA 02703 USA  OTY 1  904652
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LOT SAMPLE ORA Abutment 3.0mm (AK)  DE FR ES	SBACCE (1554	NON STERRIES	Ronly		<b>C</b> <sub>0197</sub>	Stempold Dentel, LLC 23 Frank Mossberg Drive Attleboro, MA 02703 USA  OTY 1  904692 SAMPLE
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LOT SAMPLE ORA Abutment 3.0mm (AK)  DE FR ES 11	Shecif iss	NON STEPRE	Ronly		<b>C</b> <sub>0197</sub>	Stempold Dentel, LLC 23 Frank Mossberg Drive Attleboro, MA 02703 USA  OTY 1  904692 SAMPLE
LOT SAMPLE ORA Abutment 3.0mm (AK)  DE FR ES 11	SBECT USE		Ronly		<b>C</b> <sub>0197</sub>	Stempold Dentel, LLC 23 Frank Mossberg Drive Attleboro, MA 02703 USA  OTY 1  904692 SAMPLE
LOT SAMPLE ORA Abutment 3.0mm (AK)  DE FR ES 11	SBREET USE	Ziene	Renly		<b>C</b> 0197	Stempold Dentel, LLC 23 Frank Mossberg Drive Attleboro, MA 02703 USA  OTY 1  904692 SAMPLE
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LOT SAMPLE ORA Abutment 3.0mm (AK)  DE FR ES 11	Superif (155	A A			<b>6</b> 0197	Sterngold Dental, LLC 23 Frank Mossberg Drive Attleboro, MA 02703 USA  OTY 1  904692  SAHPLE Made in USA
LOT SAMPLE  ORA Abutment 3.0mm (AK)  DE FR ES 11 Rev. 11252013	Superif iss				<b>C</b> <sub>0197</sub>	Sterngold Dental, LLC 23 Frank Mossberg Drive Attleboro, MA 02703 USA  QTY 1  904692  SaftPLC Made in USA  Manufactured by: Sterngold Dental, LLC 23 Frank Mossberg Drive
LOT SAMPLE ORA Abutment 3.0mm (AK)  DE FR ES 11	SWEET CASE	STEARS.	R <sub>only</sub>		€ <sub>0197</sub>	Sterngold Dentel, LLC 23 Frank Mossberg Drive Attleboro, MA 02703 USA  OTY 1  904692  Seriffle Made in USA  Manufactured by: Sterngold Dentel, LLC 23 Frank Mossberg Drive Attleboro, MA 02703
DE   SAMPLE  ORA Abutment   3.0mm (AK)  DE   FR   ES   II    Rev. 11252013	Specif test			CAUTION		Sterngold Dental, LLC 23 Frank Mossberg Drive Attleboro, MA 02703 USA  QTY 1  904692  SaftPLC Made in USA  Manufactured by: Sterngold Dental, LLC 23 Frank Mossberg Drive
LOT SAMPLE  ORA Abutment 3.0mm (AK)  DE FR ES 11 Rev. 11252013	Secret for			CAUTION		Sterngold Dentel, LLC 23 Frank Mossberg Drive Attleboro, MA 02703 USA  OTY 1  904692  Seriffle Made in USA  Manufactured by: Sterngold Dentel, LLC 23 Frank Mossberg Drive Attleboro, MA 02703
DE   SAMPLE  ORA Abutment   3.0mm (AK)  DE   FR   ES     11  Rev. 11252013  REF   904697  LOT   SAMPLE	Saperit ford			CAUTION	€ <sub>0197</sub>	Sterngold Dentel, LLC 23 Frank Mossberg Drive Attleboro, MA 02703 USA  OTY 1  904692  Seriffle Made in USA  Manufactured by: Sterngold Dentel, LLC 23 Frank Mossberg Drive Attleboro, MA 02703
DE   SAMPLE  ORA Abutment   3.0mm (AK)  DE   FR   ES   II    Rev. 11252013	Sacrif for			CAUTION		Sterngold Dental, LLC 23 Frank Mossberg Drive Attleboro, MA 02703 USA  OTY 1  904692  SAHFLE Made in USA  Manufactured by: Sterngold Dental, LLC 23 Frank Mossberg Drive Attleboro, MA 02703 USA
DE ORA Abutment 3.0mm (AK)  DE FR ES III  Rev. 11252013  REF 904697  LOT SAMPLE ORA Abutment 3.0mm (BF)	Sanctification			CAUTION		Sterngold Dentel, LLC 23 Frank Mossberg Drive Attleboro, MA 02703 USA  OTY 1  904692  Seriffle Made in USA  Manufactured by: Sterngold Dentel, LLC 23 Frank Mossberg Drive Attleboro, MA 02703
LOT SAMPLE  ORA Abutment 3.0mm (AK)  DE   FR   ES   11  Rev. 11252013  REF   904697  LOT SAMPLE  ORA Abutment 3.0mm (BF)  DE	Superity field			CAUTION		Sterngold Dental, LLC 23 Frank Mossberg Drive Attleboro, MA 02703 USA  OTY 1  9044692  SAPIFLE Made in USA  Manufactured by: Sterngold Dental, LLC 23 Frank Mossberg Drive Attleboro, MA 02703 USA  OTY 1
DE ORA Abutment 3.0mm (AK)  DE FR ES III  Rev. 11252013  REF 904697  LOT SAMPLE ORA Abutment 3.0mm (BF)	Superity for a			CAUTION		Sterngold Dental, LLC 23 Frank Mossberg Drive Attleboro, MA 02703 USA  OTY 1  904692  SAHFLE Made in USA  Manufactured by: Sterngold Dental, LLC 23 Frank Mossberg Drive Attleboro, MA 02703 USA
LOT SAMPLE  ORA Abutment 3.0mm (AK)  DE   FR   ES   11  Rev. 11252013  REF   904697  LOT SAMPLE  ORA Abutment 3.0mm (BF)  DE	Sabelty find			CAUTION		Sterngold Dental, LLC 23 Frank Mossberg Drive Attleboro, MA 02703 USA  OTY 1  904692  SaftPLC Made in USA  Manufactured by: Sterngold Dental, LLC 23 Frank Mossberg Drive Attleboro, MA 02703 USA  OTY 1
DE	Sancti for			CAUTION		Sterngold Dental, LLC 23 Frank Mossberg Drive Attleboro, MA 02703 USA  OTY 1  904692  Made in USA  Manufactured by: Sterngold Dental, LLC 23 Frank Mossberg Drive Attleboro, MA 02703 USA  OTY 1

# **ORA Implant Abutment System**

The ORA Abutment System is designed for use with overdentures or partial dentures, retained in whole or in part by endosseous implants in the mandible or maxilla.

#### **Features**

Made for most popular implants

**Benefits** 

Can be used to retain many overdentures fabricated today

Made from Titanium Alloy and titanium nitride coated

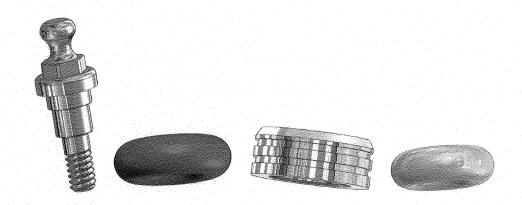
Will function properly for a long period of time

Rubber O-Ring is easily replaced

Maintenance is quick and inexpensive

**ORA** Implant Abutments transfer less force

Chances of success are greater than more ridge OV abutments





Sterngold Dental, LLC 23 Frank Mossberg Drive Attleboro, MA 02703 Tel: 508.226.5660 / 800.243.9942 www.sterngold.com

# ATTACHMENT F

# PACKAGING, STERILIZATION AND PYROGENICITY

#### PACKAGING, STERILIZATION AND PYROGENICITY

# Packaging The ORA Implant Abutments are packaged in a sealed pouch. There is no sterile barrier in the prosthetic package. Devices are supplied non-sterile and there is no shelf life. The pouch is 4x9 inches outer diameter and manufactured from paper and (b)(4) (b)(4)

#### Cleaning/Sterilization Information

The autoclave is to be used according to manufacturer instructions. The health care facility should monitor the sterilizer for the facility according to an FDA recognized sterility assurance standard such as ANSI/AAMI ST79.

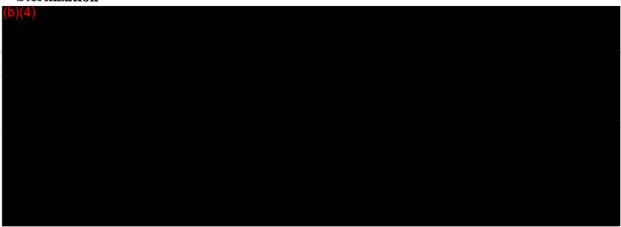
#### Cleaning

Use the following guidelines for cleaning products:

(b)(4)

Cleaning Validation
(b)(4)

#### Sterilization





#### **Pyrogenicity**

Like other currently marketed Sterngold dental implant products, the proposed ORA Implant Abutments are not labeled as non-pyrogenic.

#### **Expiration Dating**

Like other currently marketed Sterngold prosthetic products, the proposed ORA Implant Abutments do not have an expiration date. Device is supplied non-sterile.

# Controlled Document

55

# ATTACHMENT G

## TRUTHFUL AND ACCURATE STATEMENT

# PREMARKET NOTIFICATION TRUTHFUL AND ACCURATE STATEMENT

[As required by 21 CFR 807.87(k)]

I certify that, in my capacity as *Director of Regulatory Affairs* of Sterngold, I believe to the best of my knowledge, that all data and information submitted in this Premarket Notification are truthful and accurate and no material fact has been omitted.

Signature

Maria Rao
Typed Name

12/12/2013
Date

510(k) Number

# ATTACHMENT H

## **INSTRUCTIONS FOR USE**



# Sterngold ®

23 Frank Mossberg Drive Attleboro, MA 02703 800.243.9942 • 508.226.5660 www.sterngold.com

## **ORA Implant Abutments**

Instructions for Use Sterngold Dental

## **ENGLISH**

Before using the ORA Implant Abutments, the clinician in charge should carefully study the indications, contraindications, recommendations, warnings and instructions, as well as all other product-specific information (technical product description, description of the surgical and restorative technique, catalogue sheet, etc.) and fully comply with them. Detailed instructions over and above those contained in these instructions for use can be found in the technical user's guide. It is also recommended to attend the appropriate user-training courses. The aforementioned documents and details of the training courses may be obtained from the appropriate representatives in the various countries. The manufacturer, the importer and the suppliers of the ORA Implant Abutments are not liable for complications, other negative effects or damages that might occur for reasons such as incorrect indications, unsuitable choice of material or handling thereof, unsuitable use or handling of the instruments, asepsis and so on. The clinician is responsible for any such complications or other consequences. It is also the clinician's responsibility to properly instruct and inform the patient on the functions, handling and necessary care of the product and on all known product risks.

#### INDICATIONS/INTENDED USE

The ORA Implant Abutments are indicated for use with dental implants to support and/or retain removable dental prostheses in the treatment of partially or totally edentulous patients to restore chewing function. The abutment screws directly into endosseous implants or they screw into SFI Abutments which are screwed into endosseous implants.

The ORA Implant Abutments are compatible with the following implant systems:

Implant Brand	Model
Nobel Biocare Brånemark System	3.3 Fixture, 3.75 Fixture, 4.0 Fixture, 5.0 Fixture (Old Version), 3.75 MkII Self-tapping Fixture, 4.0 MkII Self-tapping Fixture
Sterngold-ImplaMed	3.3 Hex Cylinder, 4.0 Hex Cylinder, 3.75 Standard Hex Screw, 3.75 Self-tapping Hex Screw, 3.75 Self-tapping "SST" Hex Screw, 4.0 Standard Hex Screw, 4.0 Self-tapping Hex Screw, 4.0 Self-tapping "SST" Hex Screw, 4.0 Self-tapping "SST" Hex Screw, 5.0 RP "SST" Hex Screw, 3.75 RP Acid Etched, 4.0 RP Acid Etched, 5.0 RP Acid Etched, 4.1 Stern IC (4.8 head), 3.3 Stern IC (4.8 head)
Nobel Biocare (Steri-Oss®)	3.8 HL Cylinder, 3.8 HL Threaded, 4.5 HL Threaded, 3.5 NobelReplace™, Replace® Select (NP), 4.0 NobelReplace Straight, (RP), 4.3Replace®Select&NobelReplace™ (RP)
Keystone (Lifecore)	3.75 Restore® Self-tapping Screw, 4.0 Restore® Self-tapping Screw, 3.75 Restore® External Hex Screw, 4.0 Restore® External Hex Cylinder, 4.2 Sustain® External Hex Cylinder, 3.75 Sustain® External Hex Screw, 4.0 Sustain® External Hex Screw, 4.2 Sustain® External Hex MC Cylinder, Stage-1TM (3.3 and 4.0 fixtures)
3i Implant Inovations	3.25 External Hex Miniplant®, 3.25 ICE <sup>™</sup> Miniplant®, 3.25 OSSEOTITE® Miniplant®, 3.3 Cylinder Miniplant®, 3.3 External Hex Cylinder, 3.75 ICE <sup>™</sup> Self-tapping, 3.75 OSSEOTITE®, 3.75 Self-tapping Threaded, 3.75 Standard Threaded, 4.0 External Hex Cylinder, 4.0 ICE <sup>™</sup> Self-tapping, 4.0 OSSEOTITE®, 4.0 Standard Threaded, 4.25 External Hex Cylinder, TG OSSEOTITE® (4.8 Platform), 4.0 OSSEOTITE® Certain <sup>™</sup> , 4.0 OSSEOTITE® NTCertain <sup>™</sup> , 4.0 OSSEOTITE®CERTAIN PREVAIL, 5.0 Osseotite® Certain, 5.0 Osseotite® NT Certain, 5.0 Osseotite®Certain Prevail
MTEC Corporation®	3.3 Universal Flare Cylinder, 3.75 Universal Self-tapping, 3.75 Universal Self-tapping Coated, 4.0 Spike Cylinder, 4.0 Universal Cylinder
nterpore IMZ <sup>™</sup>	3.3 Hex Cylinder, 3.75 Self-tapping Threaded, 4.0 Hex Cylinder, 4.0 Self-tapping Threaded, 4.25 Hex Cylinder
Osstem	4.1 US II, III, II Plus, III Plus, SS II, III (4.8 head)

Zimmer Dental	3.5 Bio-Vent® X <sup>™</sup> , 3.75 Swede-Vent <sup>™</sup> Conical Neck CST, 3.75 Swede-Vent <sup>™</sup> Standard, 4.0
	Swede-Vent <sup>TM</sup> Standard, 4.0 Bio-Vent® X <sup>TM</sup> , 3.25 Micro-Vent® (3.5 head), 3.3 Screw-Vent® (3.5
Records p	processed () ਜਹਿੰਦੇ ਸਿੰਘ ਅੰਗਰ (ਕਰੀ ਸ਼ਿਭਰ) ਸ਼ੁਕਰ ਨੇ ਨਿਰਾਆ ਪ੍ਰਦਾਸ਼ ਉੱਤੇ ਸ਼ਿਭਰ) ਜਹਿੰਦੇ ਸਾਹਿੰਦੇ (ਕਰੀ ਸਾਹਿੰਦੇ ਸਿੰਘ ਕਰੀ
	head), 5.3 Core-Vent® (4.5 head), 3.7 Tapered Swiss Plus <sup>™</sup> (4.8 platform), 4.8 Tapered Swiss
	head), 5.3 Core-Vent® (4.5 head), 3.7 Tapered Swiss Plus <sup>™</sup> (4.8 platform), 4.8 Tapered Swiss Plus <sup>™</sup> 4.1 Straight Swiss Plus <sup>™</sup> , 4.8 Straight Swiss Plus <sup>™</sup>
Zimmer (Calcitek®, Centerpulse)	3.75 ThreadLoc <sup>TM</sup>
Straumann	ITI TE™ 3.3 (4.8 head), ITI 3.3 Std & Std Plus (4.8 head), ITI TE™ 4.1 (4.8 head), ITI 4.1 Std. & Std.
	Plus (4.8 head), ITI, 4.8 Std. & Std. Plus (4.8 head)
Biolok International	4.5 Silhouette Screw, 4.0 Micro-Lok Screw, 4.0 Micro-Lok Cylinder, 3.75 Micro-Lok Screw, 3.3
_ <u></u>	Micro-Lok Cylinder
Bud	3.25 Bud Screwvent, 3.75 Bud Screwvent
INNOVA	4.1 ENDOPORE® External Connection, 4.0 ENTEGRATM External Connection
OIC	3.0 Osteo Standard ST, 3.25 Osteo Standard ST, 3.75 Osteo Standard ST
MIS IMPLANTS	3.3mm Internal Hex, 3.75mm Internal Hex, 4.20mm Internal Hex, 5.0mm Internal Hex
BioHorizons®	3.5 Internal, 4.0 Internal, 4.5 Internal, 3.5 Single Stage, 4.5 Single Stage
Implant Direct	Legacy 3.5mm, Legacy 4.5mm, RePlant™ 4.3mm, RePlant™ 3.5mm, 3.7mm ScrewPlant, 4.7mm
	ScrewPlant
Minimatic/Stryker	3.3 External Hex Cylinder, 3.75 External Hex Screw, 4.0 External Hex Cylinder, 4.0 External Hex
	Screw, 4.75 External Hex Screw, 5.0 External Hex Cylinder
Straumann	Straumann Bone Level RC, Blue Sky Bio Square Taper RC
Straumann	Straumann Bone Level NC, Blue Sky Bio Square Taper NC
Ankylos	Ankylos
Nobel Biocare	Nobel Replace WP, Nobel Replace Select WP, NobelSpeedy Replace WP, Implant Direct 5.0
	RePlant, BlueSky Bio 5.0 Trilobe
Nobel Biocare	Nobel Conical Connection RP
Nobel Biocare	Nobel Conical Connection NP, Blue Sky Bio Max
Astra Dental	Astra 4.5 / 5.0, Blue Sky Bio Conus 12 4.5 / 5.0
Astra Dental	Astra 3.5 / 4.0, Blue Sky Bio Conus 12 3.5 / 4.0
Zimmer Dental	Zimmer TSV 5.7mm, Implant Direct Legacy 5.7, BioHorizon 5.7

#### CONTRAINDICATIONS

The ORA Implant Abutments can only be screwed into compatible Implant. They should not be used by anyone with allergies or hypersensitivity to titanium alloy. Ti 6Al 4V.

#### WARNINGS

The ORA Implant Abutments should not be used unless the dental implants are stable and there are no signs of infection or severe bone loss. Poor bone quality, poor patient oral hygiene, heavy tobacco use, uncontrolled systemic diseases (diabetes, etc.), reduced immunity, alcoholism, drug addiction, and psychological instability may contribute to lack of integration and/or subsequent implant failure. Severe bruxism, clenching, and overloading may cause bone loss, screw loosening, component fracture, and/or implant failure. Exposure to radiation and chemotherapy may impact health of the implant. Dental implant patients should be instructed to consult with their physician prior to undergoing such treatment options.

Restorative techniques required to place and restore dental implants are highly specialized and complex procedures. Practitioners should attend courses of study to familiarize themselves with implantology techniques. Improper technique can cause bone loss and implant failure.

Other relative contraindications include steroid and anticoagulant treatment which may affect the surgical site, surrounding tissue, or patient's healing function. Exposure to long-term use of bisphosphonate drugs especially with chemotherapy may impact implant survival. Careful patient selection including consultation with the attending physician is strongly recommended prior to implant treatment. Excessive mobility, bone loss, or infection may indicate the implant is failing. Any implant which appears to be failing should be treated or removed as soon as possible. If removal is necessary, curette any soft tissue from the implant site and allow site to heal as though it were an atraumatic extraction. Due to the metal conductivity, electrosurgery around the implants and intraoral abutment preparations without irrigation could result in tissue damage and implant failure. Patients should consult with their physician and imaging technician prior to undergoing an MRI procedure.

## **PRECAUTIONS**

Proper case planning is essential to the long-term success of both the prostheses and the implants. Overload is one of the key contributors to implant failure. Ensure the implant angle corrections are appropriate for the occlusal load.

#### Breakage

Implant fractures can occur when applied loads exceed the normal functional design tolerances of the implant components. Potential overloading conditions may result from deficiencies in implant numbers, lengths and/or diameters to adequately support a restoration, excessive cantilever length, incomplete abutment seating, abutment angles greater than 30 degrees, occlusal interferences causing excessive lateral forces, patient parafunction (e.g. bruxing, clenching), improper denture manufacture procedures, inadequate denture fit, and physical trauma.

#### **Changes in Performance**

It is the responsibility of the clinician to instruct the patient on all appropriate contraindications, side effects, and precautions as well as the need to seek the services of a trained dental professional if there are any changes in the performance of the implant (e.g., looseness of the prosthesis, infection or exudate around the implant, pain, or any other unusual symptoms that the patient has not been told to expect).

#### Hygiene & Maintenance

Long-term implant health is directly related to the maintenance of oral hygiene. Potential implant candidates should establish an adequate oral hygiene regimen prior to implant therapy. Following implant placement, the clinician should instruct the patient on proper tools and techniques to ensure long-term maintenance of the implant(s). The patient should also be instructed to maintain routinely scheduled prophylaxis and evaluation appointments.

2 of 4 Pages

610371 Rev A

## **General Considerations**

Control of biomechanical stresses is the key factor to long term success of the largest posts. Ever after implant integration on the patients should be monitored for signs of peri-implant bone loss and excessive attachment wear as signs of occlusal overloading.

#### **ADVERSE EFFECTS**

The following complications may occur relative to implant placement: pain, discomfort, dehiscence, delayed healing, paresthesia, hyperesthesia, edema, hemorrhage, hematoma, infection, inflammation, local and generalized allergic reaction, lack of integration, loss of bone, and loss of implant. Other adverse effects may also occur as a result of iatrogenic factors and host responses.

#### Single Use

Reuse of a single use device that has come in contact with blood, bone, tissue or other body fluids may lead to patient or user injury. Possible risks associated with reuse of a single use device include, but are not limited to, mechanical failure and transmission of infectious agents.

#### **Product Packaging**

ORA Implant Abutments are packaged in a sealed chevron pouch. These pouches are not autoclavable. Parts need to be removed from pouch prior to autoclaving and placed in an autoclavable pouch or tray.

#### **CLEANING/STERILIZATION INFORMATION**

Sterngold Dental prosthetic and ancillary components are sold non-sterile. Sterilize or disinfect according to the procedures below prior to use in patients.

The autoclave is to be used according to manufacturer instructions. The health care facility should monitor the sterilizer for the facility according to an FDA recognized sterility assurance standard such as ANSI/AAMI ST79.

Disinfection and sterilization procedures should conform to OSHA or local guidelines for blood borne pathogens.

Non Sterile Abutments shall be sterilized using steam sterilization and a gravity placement autoclave. The following sterilization parameters (method, time, and temperature) are required to achieve a 10-6 sterility assurance level (SAL). Local or national specifications should be followed where steam sterilization requirements are stricter or more conservative than those listed below.

#### Cleaning

Use the following guidelines for cleaning products:

Rinse with cool-to-lukewarm water for two-and-one-half minutes. For all parts place in an ultrasonic cleaner with an enzymatic detergent diluted with tap water per the manufacture's guidelines. Sonicate for 10 minutes. Rinse with tap water for three minutes.

#### Sterilization

Individual parts shall be placed in appropriate autoclave using steam sterilization. The following sterilization parameters (method, time, and temperature) are required to achieve a 10-<sup>6</sup> sterility assurance level (SAL).

To ensure autoclave is performing effectively, periodic use of biologic indicators should be considered.

Cycle Type: Steam Sterilization Temperature: 121°C / 250°F Exposure Time: 40 minutes Dry Time: 15 - 30 minutes

#### **Abutment Insertion and Connection to the Denture**

Choose the abutment with the proper cuff height that fits the existing implant or choose the ORA Abutment that screws into an SFI Abutment. Screw an abutment into each implant or SFI Abutment. The abutments are tightened to 20 Ncm, using a hex tool which engages the hex at the base of the ball. The o-ring or keeper is placed onto the ball, any exposed parts of the abutment are blocked out, and the o-ring/keeper is processed into the denture.

MR Safety: The ORA Implant Abutments are manufactured from a non-ferromagnetic material: 6AL-4V ELI titanium.

Titanium is usually recommended for long term implantable devices because it is safe and completely non-magnetic, non-electrically conductive and non-RF reactive eliminating all of the primary potential threats during an MRI procedure.

The ORA Implant Abutments have not been evaluated for safety and compatibility in the MR environment. The ORA Implant Abutments have not been tested for heating or migration in the MR environment.

The proposed devices do not contain or utilize software.

Manufactured and Distributed by: Sterngold Dental, LLC 23 Frank Mossberg Drive Attleboro, MA 02703-0967 USA 1-800-243-9942 or 508-226-5660



European Representative: Federico Perex San Prudencio 25 Vitoria 01005 Spain

Ph: +34 945 230 736 Fax: +34 945 230 236

I	Label Symbol	Used For	Symbol	Used For
1		Do not reuse	NON	Symbol for Non- Sterile
	REF	Catalog number	LOT	Batch code
		Manufacturer		Caution, consult accompanying documents
	<b>k</b> only	Symbol for "Use by Prescription only"	CE	Symbol for "European Conformity"
	EC REP	Authorized representative in the European Community		

# **ATTACHMENT I**

**510 (k) Summary** 

## 510(k) Summary

Sponsor:

Sterngold Dental, LLC 23 Frank Mossberg Drive

Attleboro, MA 02703

Contact:

Maria Rao, QA/RA Director Ph: 508-226-5660 ext 1206

Trade Name:

**ORA** Implant Abutments

Common Name:

Implant Abutments

Classification Name: Endosseous Dental Implant Abutment

Classification:

According to Section 513 of the Federal Food, Drug, and

Cosmetic Act, the device classification is Class II

**Product Code:** 

NHA (21CFR 872.3630)

Legally Marketed Device to which Equivalence is claimed (Predicate Devices):

Predicate Device(s): K900099, K130183.

K900099

The O-Ring System – ORS

K130183

SFI Bar® Implant Abutments for 7 Platforms

## **Description of Device:**

The ORA Implant Abutment is a precision machined ball shaped abutment that connects a compatible dental implant system with a removable partial or complete overdenture. The implant abutment is screwed into the dental implant. Connection to and retention of a denture is provided by a rubber o-ring, which may or may not be held within a metal housing. There are two color o-rings, a red processing o-ring and a white final o-ring. Connection and retention may also be provided by a plastic keeper that is processed into the denture.

The bottom portion of the abutment (cuff area to end of threads) is an exact replica of the SFI Implant Abutments previously cleared by K130183.

ORA Implant Abutments are available in sixteen different platforms and each platform is compatible with one or more implant types. Table 1 demonstrates implant/abutment compatibility. The difference between each platform is the internal connection with the specific implant. This connection has been previously cleared by K130183 – SFI Abutments.

The devices are supplied non-sterile, and there is no shelf life.

## **Abutment Insertion**

Choose the abutment with the proper cuff height that fits the existing implant or choose the ORA Abutment that screws into an SFI Abutment. Screw an abutment into each implant or SFI Abutment. The abutments are tightened to 20 Ncm, using a hex tool which engages the hex at the base of the ball.

The o-ring or keeper is placed onto the ball, any exposed parts of the abutment are blocked out, and the o-ring/keeper is processed into the denture.

## Intended Use of the Device:

The ORA Implant Abutments are indicated for use with dental implants to support and/or retain removable dental prostheses in the treatment of partially or totally edentulous patients to restore chewing function. The abutment screws directly into endosseous implants.

## **Summary Technological Characteristics:**

The proposed implant abutments are substantially equivalent to the currently marketed predicate devices. The intended use, basic design, fundamental operating principles and manufacturing procedures are the same as the predicate devices.

The material of the implant abutments conform to ASTM F136, Wrought Titanium 6 Aluminum-4 Vanadium ELI Alloy.

## Comparison/Compatibility

## Substantial Equivalence:

The proposed implant abutments are substantially equivalent to the currently marketed predicate devices. The intended use, basic design, fundamental operating principles and manufacturing procedures are the same as the predicate devices.

To ensure compatibility the following process was carried out: The implant abutments were designed and developed, and manufactured according to manufacturer's specifications and controlled procedures. A validation protocol was done in accordance with Design Control requirements per FDA CFR820.30.

Table 2 summarizes the substantial equivalence comparison to the predicate devices.

## Performance Data:

Application and functional testing have been conducted to evaluate the performance characteristics of the ORA Implant Abutments. The test methods used were the same as in predicate devices. Testing has shown that the ORA Implant Abutments included in this application are equivalent in performance characteristics to its predicate devices. The acceptance criteria were met.

# **Summary of Testing to Demonstrate Safety and Effectiveness / Conclusion:**

Non-clinical test data was used to support the substantially equivalence claim. Clinical testing was not necessary. The non-clinical testing consisted of tolerance analysis of platforms to identify worst case test samples. Fatigue testing was not done as the basic design is the same as the predicate devices. The evaluation was based on FDA guidance "Class II Special Controls Guidance Document: Root-Form Endosseous Dental Implants and Endosseous Dental Implant Abutments." Torque tests, application and functional tests have been carried out.

The summary of technological characteristics as well as application and functional testing indicate that the device is safe and effective for its intended use and performs as well or better than the predicate devices.

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## STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that refer-
ences a national or international standard. A separate report is required for each standard referenced in the 510(k).
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STANDARD TITLE <sup>1</sup> ASTM F136-12a Standard Specification for Wrough	ght Titanium-6	Aluminum-4 Vanadium ELI Alloy for Surgical	Implant	Арр
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FORM FDA 3654 (12/10)

Page 1

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Department of Health and Human Services Food and Drug Administration

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FORM FDA 3654 (12/10)

Page 1

PSC Graphics (301) 443-6740 EF

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STANDARD TITLE 1  AAMI/ANSI/ISO 10993-1:2009, Biological evaluation of medical devices -Part 1: Evaluation and testing within a	a risk maı	nagement.			
Please answer the following questions	Yes	No			
Is this standard recognized by FDA <sup>2</sup> ?	$\boxtimes$				
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Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?		$\boxtimes$			
Is a summary report <sup>4</sup> describing the extent of conformance of the standard used included in the 510(k)?					
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Department of Health and Human Services Food and Drug Administration

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STANDARD TITLE 1 AAMI/ANSI/ISO 10993-5:2009, Biological evaluation of medical devices Part 5: Tests for In Vitro	cytotoxicity.				
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Was a third party laboratory responsible for testing conformity of the device to this standard in the 510(k)?		$\boxtimes$			
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FORM FDA 3654 (12/10)

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F	Packaging, Sterilization and Pyrogeni	icity	Yes No N/A
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Food : Office 1350 I	rtment of Health and Human Services and Drug Administration e of Chief Information Officer Piccard Drive, Room 400 ville, MD 20850	An agency may not conduct or spo required to respond to, a collection displays a currently valid OMB co.	n of information unless it

Department of Health and Human Services Food and Drug Administration

## STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be con ences a national or international standard. A separate repo	npleted by the applicant when submitting a ort is required for each standard referenced	510(k) I in the 5	that refer- 10(k).
TYPE OF 510(K) SUBMISSION			
☐ Traditional ☐ Special			
STANDARD TITLE <sup>1</sup> ASTM F2459-12 Standard Test Method for Extracting Residue fi			
Please answer the following questions		Yes	No
Is this standard recognized by FDA <sup>2</sup> ?		$\boxtimes$	
FDA Recognition number <sup>3</sup>		# 8-334	1
Was a third party laboratory responsible for testing conformin the 510(k)?	nity of the device to this standard identified		
Is a summary report <sup>4</sup> describing the extent of conformance 510(k)?			X
Does the test data for this device demonstrate conformity to pertains to this device?	·	$\boxtimes$	
Does this standard include acceptance criteria?		Ø	
Does this standard include more than one option or selection of the summary report table.			
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Were deviations or adaptations made beyond what is speci If yes, report these deviations or adaptations in the summar			
Were there any exclusions from the standard?  If yes, report these exclusions in the summary report table.			
Is there an FDA guidance <sup>6</sup> that is associated with this stand If yes, was the guidance document followed in preparation of Title of guidance:			
1 The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication] 2 Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html 3 http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm 4 The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device: and the name and address of the test laboratory or	certification body involved in conformance assessme standard. The summary report includes information of utilized during the development of the device.  The supplemental information sheet (SIS) is addition which is necessary before FDA recognizes the stand http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cf search.cfm  The online search for CDRH Guidance Documents of www.fda.gov/cdrh/guidance.html	on all stand; nal informati dard. Found Standards/	on d at

FORM FDA 3654 (12/10)

Page 1

PSC Graphics (301) 443-6740 EF

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SECTION NUMBER F	SECTION TITLE Packaging, Sterilization and Pyrogenicity		CONFORMANCE?  X Yes No N/A
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Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services

# Food and Drug Administration STANDARDS DATA REPORT FOR 510(k)s

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ences a national or international standard. A separate report is required for each standard referenced in the 510(k).

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FORM FDA 3654 (6/11)

Page 1

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mormation sheet (SIS	), a deviation to adapt the standard to the	ne device, or any adaptation of a section.	
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FORM FDA 3654 (6/11)

Form Approved: OMB No. 0910-0120, Expiration Date: 12/31/13

Department of Health and Human Services Food and Drug Administration

	STANDARDS DATA REPORT FOR 510(k)s (To be filled in by applicant)		
	This report and the Summary Report Table are to be completed by the applicant when submitting a ences a national or international standard. A separate report is required for each standard referenced	510(k) t I in the 5	that refer- 10(k).
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	☐ Traditional ☐ Special ☑ Abbreviated		
ı	STANDARD TITLE		
	0)(4)		
	Please answer the following questions	Yes	No
	Is this standard recognized by FDA <sup>2</sup> ?		
	FDA Recognition number <sup>3</sup>	# <mark>(b)(4)</mark>	
	Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	$\boxtimes$	
	Is a summary report <sup>4</sup> describing the extent of conformance of the standard used included in the 510(k)?  If no, complete a summary report table.	$\boxtimes$	
	Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	$\boxtimes$	

Were there any deviations or adaptations made in the use of the standard?	
Were deviations or adaptations made beyond what is specified in the FDA SIS?	$\boxtimes$
Were there any exclusions from the standard?	$\boxtimes$

Does this standard include acceptance criteria?

Does this standard include more than one option or selection of tests?

If yes, report these exclusions in the summary report table.  $\boxtimes$ Is there an FDA guidance 6 that is associated with this standard?..... If yes, was the guidance document followed in preparation of this 510k? ..... Title of guidance:

- 1 The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]
- <sup>2</sup> Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/ DeviceRegulationandGuidance/Standards/default.htm

If no, include the results of testing in the 510(k).

If yes, report options selected in the summary report table.

- 3 http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm
- 4 The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and
- address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.
- s The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http:// www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm
- 6 The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ GuidanceDocuments/default.htm

FORM FDA 3654 (6/11)

Page 1

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Records processed under FOIA Request # 2016-1128; Released by CDRH on 09-06-2016.



Tel: (508) 226-5660

Cust. Serv: (800) 243-9942

Fax: (508) 226-5473 Toll Free Fax: (800) 531-2685

23 Frank Mossberg Drive · Attleboro, MA 02703 http://www.sterngold.com

Alloys Attachments Implants Restorative Systems

FDA CDRH DMC JAN 1 3 2014

Received

## **ECOPY COVER LETTER**

January 10, 2014

U.S. Food and Drug Administration Center for Devices ar d Radiological Health Document Mail Center-W066-0609 10903 New Hampshire Avenue Silver Spring, MD 20993-0002

RE: Abbreviated \$10(k) Premarket Notification K133791 - ORA Implant Abutment System

I am providing one eCopy on CD containing eleven (11) PDF files numbered as 001 - 011.

The eCopy is an exac: duplicate of the paper copy being submitted.

Should you have any questions, please contact me at 508.226.5660 ext: 1206.

Sincerely,

Maria Rao

Director of Regulatory Affairs

Sterngold Dental LLC



Tel: (508) 226-5660 Cust. Serv: (800) 243-9942 Fax: (508) 226-5473

Fax: (508) 226-5473 Toll Free Fax: (800) 531-2685

23 Frank Mossberg Drive · Attleboro, MA 02703 http://www.sterngold.com

Alloys Attachments Implants Restorative Systems

## **ECOPY COVER LETTER**

January 10, 2014

U.S. Food and Drug Administration Center for Devices and Radiological Health Document Mail Center-W066-0609 10903 New Hampshire Avenue Silver Spring, MD 20993-0002

RE: Abbreviated 510(k) Premarket Notification

K133791 - ORA Implant Abutment System

I am providing one eCopy on CD containing eleven (11) PDF files numbered as 001 - 011.

The eCopy is an exact duplicate of the paper copy being submitted.

Should you have any questions, please contact me at 508.226.5660 ext: 1206.

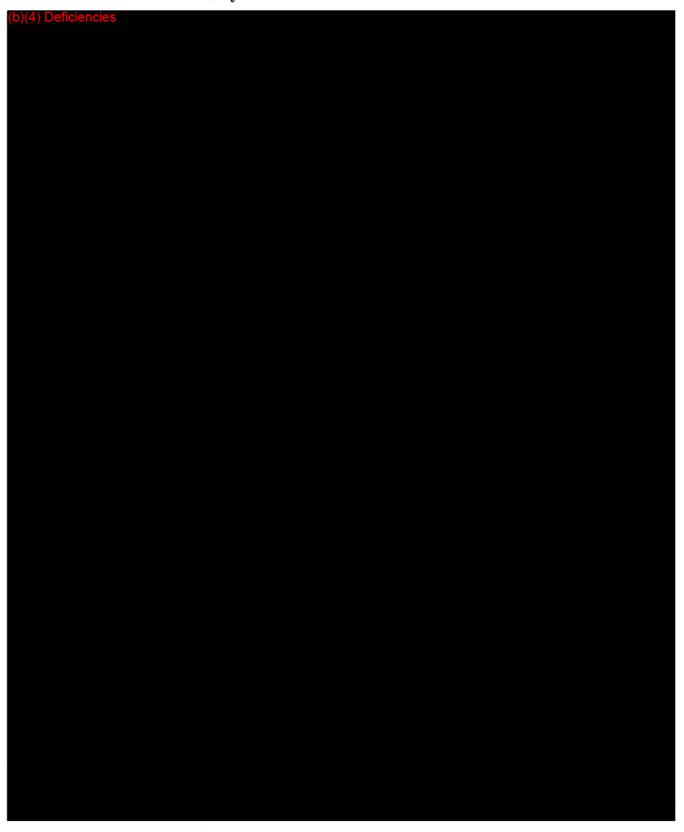
Sincerely,

Maria Rao

**Director of Regulatory Affairs** 

Sterngold Dental LLC

## K133791 ORA Abutment System





Maria Rao Director of QA & Regulatory Affairs Sterngold Dental, LLC January 9, 2014

# INDICATIONS FOR USE STATEMENT

January 9, 2014

Able Reviewed 516(16) Company 10 (16) Able Reviewed 16 (16) Able Review

510(k)	Number	(if	known):	

Device Name: ORA Implant Abutment System

## Indications for Use:

The ORA Implant Abutment System is indicated for use with dental implants to support and/or retain removable dental prostheses in the treatment of partially or totally edentulous patients to restore chewing function. The abutment screws directly into endosseous implants or they screw into SFI Abutments which are screwed into endosseous implants.

Implant Brand	Model
Nobel Biocare Brånemark System	3.3 Fixture, 3.75 Fixture, 4.0 Fixture, 5.0 Fixture (Old Version), 3.75 MkII Self-tapping Fixture, 4.0 MkII Self-tapping Fixture
Sterngold-ImplaMed	3.3 Hex Cylinder, 4.0 Hex Cylinder, 3.75 Standard Hex Screw, 3.75 Self-tapping Hex Screw, 3.75 Self-tapping "SST" Hex Screw, 4.0 Standard Hex Screw, 4.0 Self-tapping Hex Screw, 4.0 Self-tapping "SST" Hex Screw, 4.0 Self-tapping "SST" Hex Screw, 4.0 Self-tapping "SST" Hex Screw, 3.75 RP Acid Etched, 4.0 RP Acid Etched, 5.0 RP Acid Etched, 4.1 Stern IC (4.8 head), 3.3 Stern IC (4.8 head)
Nobel Biocare (Steri-Oss®)	3.8 HL Cylinder, 3.8 HL Threaded, 4.5 HL Threaded, 3.5 NobelReplace™, Replace® Select (NP), 4.0 NobelReplace Straight, (RP), 4.3Replace®Select&NobelReplace™ (RP)
Keystone (Lifecore)	3.75 Restore® Self-tapping Screw, 4.0 Restore® Self-tapping Screw, 3.75 Restore® External Hex Screw, 4.0 Restore® External Hex Screw, 4.0 Restore® External Hex Cylinder, 4.2 Sustain® External Hex Cylinder, 3.75 Sustain® External Hex Screw, 4.0 Sustain® External Hex Screw, 4.2 Sustain® External Hex MC Cylinder, Stage-1TM (3.3 and 4.0 fixtures)
3i Implant Inovations	3.25 External Hex Miniplant®, 3.25 ICE <sup>™</sup> Miniplant®, 3.25 OSSEOTITE® Miniplant®, 3.3 Cylinder Miniplant®, 3.3 External Hex Cylinder, 3.75 ICE <sup>™</sup> Self-tapping, 3.75 OSSEOTITE®, 3.75 Self-tapping Threaded, 3.75 Standard Threaded, 4.0 External Hex Cylinder, 4.0 ICE <sup>™</sup> Self-tapping, 4.0 OSSEOTITE®, 4.0 Standard Threaded, 4.25 External Hex Cylinder, TG OSSEOTITE® (4.8 Platform), 4.0 OSSEOTITE® Certain <sup>™</sup> , 4.0 OSSEOTITE® NTCertain <sup>™</sup> , 4.0 OSSEOTITE® CERTAIN PREVAIL, 5.0 Osseotite® Certain, 5.0 Osseotite® NT Certain, 5.0 Osseotite® Certain Prevail
IMTEC Corporation®	3.3 Universal Flare Cylinder, 3.75 Universal Self-tapping, 3.75 Universal Self-tapping Coated, 4.0 Spike Cylinder, 4.0 Universal Cylinder
Interpore IMZ <sup>TM</sup>	3.3 Hex Cylinder, 3.75 Self-tapping Threaded, 4.0 Hex Cylinder, 4.0 Self-tapping Threaded, 4.25 Hex Cylinder
Osstem	4.1 US II, III, II Plus, III Plus, SS II, III (4.8 head)
Zimmer Dental	4.1 US II, III, II Plus, III Plus, SS II, III (4.8 head) 3.5 Bio-Vent® X <sup>™</sup> , 3.75 Swede-Vent <sup>™</sup> Conical Neck CST, 3.75 Swede-Vent <sup>™</sup> Standard, 4.0 Swede-Vent <sup>™</sup> Standard, 4.0 Bio-Vent® X <sup>™</sup> , 3.25 Micro-Vent® (3.5 head), 3.3 Screw-Vent® (3.5 head), 3.5 Bio-Vent® (3.5 head), 3.7 Screw-Vent® (3.5 head), 4.3 Core-Vent® (3.5 head), 4.25 Micro-Vent® (4.5 head), 4.5 Bio-Vent® (4.5 head), 4.7 Screw-Vent® (4.5 head), 5.3 Core-Vent® (4.5 head), 3.7 Tapered Swiss Plus <sup>™</sup> (4.8 platform), 4.8 Tapered Swiss Plus <sup>™</sup> 4.1 Straight Swiss Plus <sup>™</sup> , 4.8 Straight Swiss Plus <sup>™</sup>
Zimmer (Calcitek®, Centerpulse)	3.75 ThreadLoc <sup>IM</sup>
Straumann	ITI TE <sup>TM</sup> 3.3 (4.8 head), ITI 3.3 Std & Std Plus (4.8 head), ITI TE <sup>TM</sup> 4.1 (4.8 head), ITI 4.1 Std. & Std. Plus (4.8 head), ITI, 4.8 Std. & Std. Plus (4.8 head)
Biolok International	4.5 Silhouette Screw, 4.0 Micro-Lok Screw, 4.0 Micro-Lok Cylinder, 3.75 Micro-Lok Screw, 3.3 Micro-Lok Cylinder
Bud	3.25 Bud Screwvent, 3.75 Bud Screwvent
INNOVA	4.1 ENDOPORE® External Connection, 4.0 ENTEGRATM External Connection
OIC	3.0 Osteo Standard ST, 3.25 Osteo Standard ST, 3.75 Osteo Standard ST

MIS IMPLANTS	3.3mm Internal Hex, 3.75mm Internal Hex, 4.20mm Internal Hex, 5.0mm Internal Hex		
BioHorizons®	3.5 Internal, 4.0 Internal, 4.5 Internal, 3.5 Single Stage		
Implant Direct	Legacy 3.5mm, Legacy 4.5mm, RePlant™ 4.3mm, RePlant™ 3.5mm, 3.7mm ScrewPlant, 4.7mm ScrewPlant		
Minimatic/Stryker	3.3 External Hex Cylinder, 3.75 External Hex Screw, 4.0 External Hex Cylinder, 4.0 External Hex Screw, 4.75 External Hex Screw, 5.0 External Hex Cylinder		
Straumann	Straumann Bone Level RC, Blue Sky Bio Square Taper RC		
Straumann	Straumann Bone Level NC, Blue Sky Bio Square Taper NC		
Ankylos	Ankylos		
Nobel Biocare	Nobel Replace WP, Nobel Replace Select WP, NobelSpeedy Replace WP, Implant Direct 5.0 RePlant, BlueSky Bio 5.0 Trilobe		
Nobel Biocare	Nobel Conical Connection RP		
Nobel Biocare	Nobel Conical Connection NP, Blue Sky Bio Max		
Astra Dental	Astra 4.5 / 5.0, Blue Sky Bio Conus 12 4.5 / 5.0		
Astra Dental	Astra 3.5 / 4.0, Blue Sky Bio Conus 12 3.5 / 4.0		
Zimmer Dental	Zimmer TSV 5.7mm, Implant Direct Legacy 5.7, BioHorizon 5.7		

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)				
Concurrence of CDF	RH, Office of	Device Evaluation (ODE)		
Prescription Use X (Part 21 CFR 801 Subparts D)	AND/OR	Over-the -Counter Use		

# **COVER LETTER**

January 9, 2014

U.S. Food and Drug Administration Center for Devices and Radiological Health Document Mail Center-W066-0609 10903 New Hampshire Avenue Silver Spring, MD 20993-0002

RE: Abbreviated 510(k) Premarket Notification ORA Implant Abutment System

This Premarket Notification is an **Abbreviated 510(k)** as defined in FDA's March 20, 1998 Final Guidance entitled <u>The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications."</u>

The ORA Implant Abutments described in this submission is appropriate for an Abbreviated 510(k) because the proposed product was developed in accordance with and is in compliance with the following relevant FDA guidance documents and/or recognized consensus standards:

Guidance for Industry and FDA Staff Class II Special Controls Guidance
Document: Root-form Endosseous Dental Implants and Endosseous Dental
Implant Abutments. (Draft FDA Guidance; distributed for comment May 12,
2004)

Sterngold hereby requests that the Food and Drug Administration (FDA) hold confidential the information of their intent to seek 510(k) clearance for these devices. To the best of our knowledge, neither we nor anyone else has disclosed through advertising to physicians, scientists, market analysts, exporters, or other individuals, or through any other manner, our intent to seek 510(k) clearance for these devices in the United States, except employees of or consultants to our company and pursuant only to appropriate contractual arrangements with appropriate safeguards for secrecy.

There were no prior submissions for the proposed device.

This 510(k) Premarket Notification is submitted in one paper copy and one E-Copy. Should you have any questions, please contact me at 508.226.5660 ext: 1206.

Sincerely,

Maria Rao

Director of Regulatory Affairs

Sterngold Dental

# **ATTACHMENT B**

## **DEVICE DESCRIPTION**

#### **DEVICE DESCRIPTION**

This Abbreviated 510(k) Premarket Notification seeks clearance for the ORA Implant Abutments.

The ORA Implant Abutment System is a precision machined ball shaped abutment that connects a compatible dental implant system with a removable partial or complete overdenture. The implant abutment is screwed into the dental implant. Connection to and retention of a denture is provided by a rubber o-ring, which may or may not be held within a metal housing. There are two color o-rings, a red processing o-ring and a white final o-ring.

The retaining ring (metal housing) comes with the red o-ring (which is a firm rubber) inside. The retaining ring (metal housing) with the red o-ring is pushed over the wide part of the ball until seated. The stiffness of the red o-ring holds the housing in position. Any exposed areas of the abutment are blocked out so that only the metal housing is exposed. The retaining ring (metal housing) is then processed into the denture. After the material has cured, the denture is removed. The red o-ring is pulled out of the metal housing and the white o-ring is inserted into its place. The white o-ring is more flexible making insertion and removal easier. This procedure can be done in the laboratory or in the dentist's office.

The bottom portion of the ORA abutment (cuff area to end of threads) is an exact replica of the SFI Implant Abutments previously cleared by K130183.

The ORA Implant Abutment System is available in sixteen different platforms and each platform is compatible with one or more implant types. Table 1 demonstrates implant/abutment compatibility. The difference between each platform is the internal connection with the specific implant. This connection has been previously cleared by K130183 – SFI Abutments.

<b>Implant Brand</b>	Model		
Straumann [BD]	Straumann Bone Level RC, Blue Sky Bio Square Taper RC		
Straumann [BE]	Straumann Bone Level NC, Blue Sky Bio Square Taper NC		
Ankylos [AE]	Ankylos		
Nobel Biocare	Nobel Replace WP, Nobel Replace Select WP, NobelSpeedy Replace WP, Implant Direct 5.0		
[AN]	RePlant, BlueSky Bio 5.0 Trilobe		
Nobel Biocare	Nobel Conical Connection RP, Blue Sky Bio Max		
[AP]			
Nobel Biocare	Nobel Conical Connection NP		
[AY]			
Astra Dental [AJ]	Astra 4.5 / 5.0, Blue Sky Bio Conus 12 4.5 / 5.0		
Astra Dental [AK]	Astra 3.5 / 4.0, Blue Sky Bio Conus 12 3.5 / 4.0		
Zimmer Dental	Zimmer TSV 5.7mm, Implant Direct Legacy 5.7, BioHorizon 5.7		
[BF]			

Nobel Biocare	3.3 Fixture, 3.75 Fixture, 4.0 Fixture, 5.0 Fixture (Old Version), 3.75 MkII Self-tapping Fixture,
Brånemark System	4.0 MkII Self-tapping Fixture
[A] Sterngold- ImplaMed [A]	3.3 Hex Cylinder, 4.0 Hex Cylinder, 3.75 Standard Hex Screw, 3.75 Self-tapping Hex Screw, 3.75 Self-tapping "SST" Hex Screw, 4.0 Standard Hex Screw, 4.0 Self-tapping Hex Screw, 4.0 Self-tapping "SST" Hex Screw, 4.0 Self-tapping "SST" Hex Screw, 5.0 RP "SST" Hex Screw, 3.75 RP Acid Etched, 4.0 RP Acid Etched, 5.0 RP Acid Etched
Sterngold- ImplaMed [S]	4.1 Stern IC (4.8 head), 3.3 Stern IC (4.8 head)
Nobel Biocare (Steri-Oss®) [A]	3.8 HL Cylinder, 3.8 HL Threaded, 4.5 HL Threaded
Nobel Biocare (Steri-Oss®) [Z]	3.5 NobelReplace™, Replace® Select (NP)
Nobel Biocare (Steri-Oss®) [T]	4.0 NobelReplace Straight, (RP), 4.3Replace®Select&NobelReplace™ (RP)
Keystone (Lifecore) [A]	3.75 Restore® Self-tapping Screw, 4.0 Restore® Self-tapping Screw, 3.75 Restore® External Hex Screw, 4.0 Restore® External Hex Cylinder, 4.2 Sustain® External Hex Cylinder, 3.75 Sustain® External Hex Screw, 4.0 Sustain® External Hex Screw, 4.2 Sustain® External Hex MC Cylinder,
Keystone (Lifecore) [S]	Stage-1 <sup>TM</sup> (3.3 and 4.0 fixtures)
3i Implant Inovations [A]	3.25 External Hex Miniplant®, 3.25 ICE TM Miniplant®, 3.25 OSSEOTITE® Miniplant®, 3.3 Cylinder Miniplant®, 3.3 External Hex Cylinder, 3.75 ICE Self-tapping, 3.75 OSSEOTITE®, 3.75 Self-tapping Threaded, 3.75 Standard Threaded, 4.0 External Hex Cylinder, 4.0 ICE Message Self-tapping,
3i Implant Inovations [S]	TG OSSEOTITE® (4.8 Platform)
3i Implant Inovations [X]	4.0 OSSEOTITE®, 4.0 Standard Threaded, 4.25 External Hex Cylinder, 4.0 OSSEOTITE® Certain TM, 4.0 OSSEOTITE® NTCertain TM, 4.0 OSSEOTITE®CERTAIN PREVAIL, 5.0 Osseotite® Certain, 5.0 Osseotite® NT Certain, 5.0 Osseotite®Certain Prevai
IMTEC Corporation® [A]	3.3 Universal Flare Cylinder, 3.75 Universal Self-tapping, 3.75 Universal Self-tapping Coated, 4.0 Spike Cylinder, 4.0 Universal Cylinder
Interpore IMZ [A]	3.3 Hex Cylinder, 3.75 Self-tapping Threaded, 4.0 Hex Cylinder, 4.0 Self-tapping Threaded, 4.25 Hex Cylinder
Osstem [A]	4.1 US II, III, II Plus, III Plus
Osstem [S]	SS II, III (4.8 head)
Zimmer Dental[A]	3.5 Bio-Vent® X <sup>TM</sup> , 3.75 Swede-Vent TM Conical Neck CST, 3.75 Swede-Vent TM Standard, 4.0 Swede-Vent TM Standard, 4.0 Bio-Vent® X <sup>TM</sup> ,
Zimmer Dental [B]	3.25 Micro-Vent® (3.5 head), 3.3 Screw-Vent® (3.5 head), 3.5 Bio-Vent® (3.5 head), 3.7 Screw-Vent® (3.5 head), 3.75 Screw-Vent® (3.5 head), 4.3 Core-Vent® (3.5 head)
Zimmer Dental [C]	4.25 Micro-Vent® (4.5 head), 4.5 Bio-Vent® (4.5 head), 4.7 Screw-Vent® (4.5 head), 5.3
Zimmer Dental [S]	3.7 Tapered Swiss Plus TM (4.8 platform), 4.8 Tapered Swiss Plus A.1 Straight Swiss Plus A.8 Straight Swiss Plus TM
Zimmer	3.75 ThreadLocTM
(Calcitek®, Centerpulse) [A]	
Straumann [S]	ITI TE <sup>TM</sup> 3.3 (4.8 head), ITI 3.3 Std & Std Plus (4.8 head), ITI TE <sup>TM</sup> 4.1 (4.8 head), ITI 4.1 Std. & Std. Plus (4.8 head), ITI, 4.8 Std. & Std. Plus (4.8 head)

Biolok	4.5 Silhouette Screw, 4.0 Micro-Lok Screw, 4.0 Micro-Lok Cylinder, 3.75 Micro-Lok Screw,		
International [A]	3.3 Micro-Lok Cylinder		
Bud [A]	3.25 Bud Screwvent, 3.75 Bud Screwvent		
INNOVA [A]	4.1 ENDOPORE® External Connection, 4.0 ENTEGRATM External Connection		
OIC [A]	3.0 Osteo Standard ST, 3.25 Osteo Standard ST, 3.75 Osteo Standard ST		
MIS IMPLANTS			
[B]	3.3mm Internal Hex, 3.75mm Internal Hex, 4.20mm Internal Hex		
MIS IMPLANTS	5.0mm Internal Hex		
[C]			
BioHorizons® [B]	3.5 Internal, 3.5 Single Stage		
BioHorizons® [C]	4.0 Internal, 4.5 Internal, 4.5 Single Stage		
Implant Direct [B]	Legacy 3.5mm, 3.7mm ScrewPlant,		
Implant Direct C]	Legacy 4.5mm, 4.7mm ScrewPlant		
Implant Direct [T]	RePlant <sup>TM</sup> 4.3mm		
Implant Direct [Z]	RePlant™ 3.5mm		
Minimatic/Stryker	3.3 External Hex Cylinder, 3.75 External Hex Screw, 4.0 External Hex Cylinder, 4.0 External		
[A]	Hex Screw, 4.75 External Hex Screw, 5.0 External Hex Cylinder		



#### **Material Composition:**

The ORA Implant Abutments are manufactured by the same strict standards as previous Sterngold devices and from the same materials used to manufacture previously devices cleared by K130183.

ORA Implant abutment - Wrought Titanium 6 Al-4V ELI Alloy, ASTM F136.

• ORA Retaining Ring - Stainless Steel, ASTM A582.

• Red Processing O-Ring - (b)(4)
(b)(4)

• White Final O-Ring –

(21 CFR 177.2600 FDA approved ingredients intended for repeated use).

The proposed devices do not contain or utilize software.

#### Components/Accessories:

ORA Retaining Ring – 914065 Red Processing O-Ring – 909011 White Final O-Ring - 909012

**MR Safety:** The ORA Implant Abutments are manufactured from a **non-ferromagnetic** material: 6AL-4V ELI titanium.

Titanium is usually recommended for long term implantable devices because it is safe and completely non-magnetic, non-electrically conductive and non-RF reactive eliminating all of the primary potential threats during an MRI procedure.

The ORA Implant Abutments have not been evaluated for safety and compatibility in the MR environment. The ORA Implant Abutments have not been tested for heating or migration in the MR environment. These statements are included in the Instructions for Use.

The proposed ORA Implant Abutments are listed on Table B. This table is a complete list of the devices/models that need marketing clearance.

Refer to Table C for a 3D photograph of an ORA Abutment.

	D. J. J. D
	Product Description
904264	ORA 0.4MM [S]
904265	ORA 1.0MM [S]
904266	ORA 2.0MM [S]
904267	ORA 3.0MM [S]
904268	ORA 4.0MM [S]
904335	ORA 1.25MM [A]
904336	ORA 2.0MM [A]
904337	ORA 3.0MM [A]
904338	ORA 4.0MM [A]
904339	ORA 5.0MM [A]
904340	ORA 1.0MM [B]
904341	ORA 2.0MM [B]
904342	ORA 3.0MM [B]
904343	ORA 4.0MM [B]
904344	ORA 5.0MM [B]
904345	ORA 1.0MM [C]
904346	ORA 2.0MM [C]
904347	ORA 3.0MM [C]
904348	ORA 4.0MM [C]
904349	ORA 5.0MM [C]
904374	ORA 1.0MM [T]
904375	ORA 2.0MM [T]
904376	ORA 3.0MM [T]
904377	ORA 4.0MM [T]
904378	ORA 5.0MM [T]
904390	ORA 1.0MM [X]
904391	ORA 2.0MM [X]
904392	ORA 3.0MM [X]
904393	ORA 4.0MM [X]
904394	ORA 5.0MM [X]
904464	ORA 1.0MM [Z]
904465	ORA 2.0MM [Z]
904466	ORA 3.0MM [Z]
904467	ORA 4.0MM [Z]
904468	ORA 5.0MM [Z]
904469	ORA 1.0MM [BD]
904470	ORA 2.0MM [BD]
904471	ORA 3.0MM [BD]
904472	ORA 4.0MM [BD]
904474	ORA 5.0MM [BD]
904550	ORA 1.0MM [BE]
904551	ORA 2.0MM [BE]
904552	ORA 3.0MM [BE]
904553	ORA 4.0MM [BE]
004000	1-10. 1.011111 [0-1]

Product No.	<b>Product Description</b>
904554	ORA 5.0MM [BE]
904555	ORA 1.0MM [AE]
904556	ORA 2.0MM [AE]
904557	ORA 3.0MM [AE]
904558	ORA 4.0MM [AE]
904559	ORA 5.0MM [AE]
904670	ORA 1.0MM [AN]
904671	ORA 2.0MM [AN]
904672	ORA 3.0MM [AN]
904673	ORA 4.0MM [AN]
904674	ORA 5.0MM [AN]
904675	ORA 1.0MM [AP]
904676	ORA 2.0MM [AP]
904677	ORA 3.0MM [AP]
904678	ORA 4.0MM [AP]
904679	ORA 5.0MM [AP]
904680	ORA 1.0MM [AY]
904681	ORA 2.0MM [AY]
904682	ORA 3.0MM [AY]
904683	ORA 4.0MM [AY]
904684	ORA 5.0MM [AY]
904685	ORA 1.0MM [AJ]
904686	ORA 2.0MM [AJ]
904687	ORA 3.0MM [AJ]
904688	ORA 4.0MM [AJ]
904689	ORA 5.0MM [AJ]
904690	ORA 1.0MM [AK]
904691	ORA 2.0MM [AK]
904692	ORA 3.0MM [AK]
904693	ORA 4.0MM [AK]
904694	ORA 5.0MM [AK]
904695	ORA 1.0MM [BF]
904696	ORA 2.0MM [BF]
904697	ORA 3.0MM [BF]
904698	ORA 4.0MM [BF]
904699	ORA 5.0MM [BF]
914065	ORA Retaining Ring
909011	Red Processing O-Rir
909012	White Final O-Ring

#### **Indications for Use:**

The ORA Implant Abutment System is indicated for use with dental implants to support and/or retain removable dental prostheses in the treatment of partially or totally edentulous patients to restore chewing function. The abutment screws directly into endosseous implants or they screw into SFI Abutments which are screwed into endosseous implants.

Implant Brand	Model		
Nobel Biocare Brånemark System	3.3 Fixture, 3.75 Fixture, 4.0 Fixture, 5.0 Fixture (Old Version), 3.75 MkII Self-tapping Fixture, 4.0 MkII Self-tapping Fixture		
Sterngold-ImplaMed	3.3 Hex Cylinder, 4.0 Hex Cylinder, 3.75 Standard Hex Screw, 3.75 Self-tapping Hex Screw, 3.75 Self-tapping "SST" Hex Screw, 4.0 Standard Hex Screw, 4.0 Self-tapping Hex Screw, 4.0 Self-tapping "SST" Hex Screw, 4.0 Self-tapping "SST" Hex Screw, 4.0 Self-tapping "SST" Hex Screw, 3.75 RP Acid Etched, 4.0 RP Acid Etched, 5.0 RP Acid Etched, 4.1 Stern IC (4.8 head), 3.3 Stern IC (4.8 head)		
Nobel Biocare (Steri-Oss®)	3.8 HL Cylinder, 3.8 HL Threaded, 4.5 HL Threaded, 3.5 NobelReplace™, Replace® Select (NP), 4.0 NobelReplace Straight, (RP), 4.3Replace® Select&NobelReplace™ (RP)		
Keystone (Lifecore)	3.75 Restore® Self-tapping Screw, 4.0 Restore® Self-tapping Screw, 3.75 Restore® External Hex Screw, 4.0 Restore® External Hex Screw, 4.0 Restore® External Hex Cylinder, 4.2 Sustain® External Hex Cylinder, 3.75 Sustain® External Hex Screw, 4.0 Sustain® External Hex Screw, 4.2 Sustain® External Hex MC Cylinder, Stage-1TM (3.3 and 4.0 fixtures)		
3i Implant Inovations	3.25 External Hex Miniplant®, 3.25 ICE <sup>™</sup> Miniplant®, 3.25 OSSEOTITE® Miniplant®, 3.3 Cylinder Miniplant®, 3.3 External Hex Cylinder, 3.75 ICE <sup>™</sup> Self-tapping, 3.75 OSSEOTITE®, 3.75 Self-tapping Threaded, 3.75 Standard Threaded, 4.0 External Hex Cylinder, 4.0 ICE <sup>™</sup> Self-tapping, 4.0 OSSEOTITE®, 4.0 Standard Threaded, 4.25 External Hex Cylinder, TG OSSEOTITE® (4.8 Platform), 4.0 OSSEOTITE® Certain <sup>™</sup> , 4.0 OSSEOTITE® NTCertain <sup>™</sup> , 4.0 OSSEOTITE®CERTAIN PREVAIL, 5.0 Osseotite® Certain, 5.0 Osseotite® NT Certain, 5.0 Osseotite®Certain Prevail		
IMTEC Corporation®	3.3 Universal Flare Cylinder, 3.75 Universal Self-tapping, 3.75 Universal Self-tapping Coated, 4.0 Spike Cylinder, 4.0 Universal Cylinder		
Interpore IMZ <sup>™</sup>	3.3 Hex Cylinder, 3.75 Self-tapping Threaded, 4.0 Hex Cylinder, 4.0 Self-tapping Threaded, 4.25 Hex Cylinder		
Osstem	4.1 US II, III, II Plus, III Plus, SS II, III (4.8 head)		
Zimmer Dental	3.5 Bio-Vent® X <sup>TM</sup> , 3.75 Swede-Vent <sup>TM</sup> Conical Neck CST, 3.75 Swede-Vent <sup>TM</sup> Standard, 4.0 Swede Vent <sup>TM</sup> Standard, 4.0 Bio-Vent® X <sup>TM</sup> , 3.25 Micro-Vent® (3.5 head), 3.3 Screw-Vent® (3.5 head), 3.5 Bio-Vent® (3.5 head), 3.7 Screw-Vent® (3.5 head), 3.75 Screw-Vent® (3.5 head), 4.3 Core-Vent® (3.5 head), 4.25 Micro-Vent® (4.5 head), 4.5 Bio-Vent® (4.5 head), 4.7 Screw-Vent® (4.5 head), 5.3 Core-Vent® (4.5 head), 3.7 Tapered Swiss Plus <sup>TM</sup> (4.8 platform), 4.8 Tapered Swiss Plus <sup>TM</sup> 4.1 Straight Swiss Plus <sup>TM</sup> , 4.8 Straight Swiss Plus <sup>TM</sup>		
Zimmer (Calcitek®, Centerpulse)	3.75 ThreadLoc <sup>1M</sup>		
Straumann	ITI TE <sup>™</sup> 3.3 (4.8 head), ITI 3.3 Std & Std Plus (4.8 head), ITI TE <sup>™</sup> 4.1 (4.8 head), ITI 4.1 Std. & Std. Plus (4.8 head), ITI, 4.8 Std. & Std. Plus (4.8 head)		
Biolok International	4.5 Silhouette Screw, 4.0 Micro-Lok Screw, 4.0 Micro-Lok Cylinder, 3.75 Micro-Lok Screw, 3.3 Micro-Lok Cylinder		
Bud	3.25 Bud Screwvent, 3.75 Bud Screwvent		
INNOVA	4.1 ENDOPORE® External Connection, 4.0 ENTEGRATM External Connection		
OIC	3.0 Osteo Standard ST, 3.25 Osteo Standard ST, 3.75 Osteo Standard ST		
MIS IMPLANTS	3.3mm Internal Hex, 3.75mm Internal Hex, 4.20mm Internal Hex, 5.0mm Internal Hex		
BioHorizons®	3.5 Internal, 4.0 Internal, 4.5 Internal, 3.5 Single Stage, 4.5 Single Stage		
Implant Direct	Legacy 3.5mm, Legacy 4.5mm, RePlant™ 4.3mm, RePlant™ 3.5mm, 3.7mm ScrewPlant, 4.7mm ScrewPlant		
Minimatic/Stryker	3.3 External Hex Cylinder, 3.75 External Hex Screw, 4.0 External Hex Cylinder, 4.0 External Hex Screw, 4.75 External Hex Screw, 5.0 External Hex Cylinder		
Straumann	Straumann Bone Level RC, Blue Sky Bio Square Taper RC		
Straumann	Straumann Bone Level NC, Blue Sky Bio Square Taper NC		
Ankylos	Ankylos		
Nobel Biocare	Nobel Replace WP, Nobel Replace Select WP, NobelSpeedy Replace WP, Implant Direct 5.0 RePlant, BlueSky Bio 5.0 Trilobe		
Nobel Biocare	Nobel Conical Connection RP		
Nobel Biocare	Nobel Conical Connection NP, Blue Sky Bio Max		
Astra Dental	Astra 4.5 / 5.0, Blue Sky Bio Conus 12 4.5 / 5.0		
Astra Dental	Astra 3.5 / 4.0, Blue Sky Bio Conus 12 3.5 / 4.0		
Zimmer Dental	Zimmer TSV 5.7mm, Implant Direct Legacy 5.7, BioHorizon 5.7		

# ATTACHMENT C SUBSTANTIAL EQUIVALENCE SECTION 7

#### SUBSTANTIAL EQUIVALENCE

The proposed ORA Implant Abutments are substantially equivalent to the currently marketed implant predicate devices. The intended use, basic design, fundamental operating principles and manufacturing procedures are the same as the predicate devices. To ensure compatibility the following process was carried out: The implant abutments were designed, developed, and manufactured according to manufacturer's specifications and controlled procedures. A validation protocol was done in accordance with Design Control requirements per FDA CFR820.30.

K900099 The O-Ring System – ORS K130183 SFI Bar® Implant Abutments for 7 Platforms

Compatibility was determined by comparing the design features including diameters, lengths, cuff sizes, materials, implant/abutment interface connection, and intended use of the proposed device to predicate devices.

The ORA Abutments are an exact replica of the ORS abutments previously cleared by K900099. There are no differences between the proposed device and the predicate device, which we claim substantial equivalence (K900099). Based on this the proposed device renders no NSE.

Substantial equivalence was established based on intended use, design, materials, chemical composition, manufacturing process, performance, safety, effectiveness, labeling, and biocompatibility.

Application testing consisted of Manufacturer's implants were purchased and was performed to ensure full compatibility.

Continuous compatibility with manufacturer's implants indicated on this application and respective abutments will be verified every months by (b)(4) to ensure compatibility.

The summary of technological characteristics, tolerance analysis, application and functional testing indicate that the device is safe and effective for its intended use and performs as well or better than the predicate devices.

Table A summarizes the substantial equivalence comparison to the predicate devices.

#### Table A

Attribute	Candidate	Predicate Device	Predicate Device
	The ORA Implant Abutment Sterngold Dental, LLC	The O-Ring System – ORS Attachments International, Inc. K900099	SFI Implant Abutments Sterngold Dental, LLC K130183
Design/Construction	Machined, screw-retained	Machined, screw-retained	Machined, screw-retained
<b>Anatomical Site</b>	Oral Cavity	Oral Cavity	Oral Cavity
Device Material	Wrought Titanium-6AL-4 Vanadium ELI Alloy	Wrought Titanium-6AL-4 Vanadium ELI Alloy	Wrought Titanium-6AL-4 Vanadium ELI Alloy
Indications for Use	Indicated for use with dental implants to support and/or retain removable dental prostheses in the treatment of partially or totally edentulous patients to restore chewing function. The abutment screws directly into endosseous implants.	The ORS Implant Abutments are intended for use with dental implants as a support or attachment for prosthetic restoration. The abutment screws directly into the implant.	The SFI-Bar® Implant Abutments are indicated for use with dental implant bodies/fixtures to support and /or retain removable dental prostheses for partially or totally edentulous patients to restore chewing function.
Operating Principle/ Basic Design	Abutment Implant connection: Screw fixation	Abutment Implant connection: Screw fixation	Abutment Implant connection: Screw fixation
	Connecting principle to overdenture: Retentive system  Cleaning procedures for patient: Common procedure for oral	Connecting principle to overdenture: Retentive system  Cleaning procedures for patient: Common procedure for oral	Connecting principle to overdenture: Retentive system  Cleaning procedures for patient: Common procedure
	hygiene  Patient handling: Common cleaning and insertion of denture	hygiene  Patient handling: Common cleaning and insertion of denture	patient: Common procedure for oral hygiene  Patient handling: Common cleaning and insertion of denture
Packaging,	Produced in a controlled CNC	Produced in a controlled CNC	Produced in a controlled CNC
materials and processes	machine process, previously validated	machine process, previously validated	machine process, previously validated
	Packaging: Pouch Non-sterile	Packaging: Pouch Non-sterile	Packaging: Pouch Non-sterile

# ATTACHMENT D CONFORMITY WITH FDA GUIDANCE DOCUMENT

**SECTION 8** 

#### CONFORMITY WITH FDA GUIDANCE DOCUMENTS

Sterngold certifies that the proposed The ORA Implant Abutments were developed in accordance with and meet the requirements contained in the following consensus standards:

Guidance for Industry and FDA Staff Class II Special Controls Guidance
Document: Root-form Endosseous Dental Implants and Endosseous Dental
Implant Abutments. (Draft FDA Guidance; distributed for comment May 12,
2004)

The proposed device was designed and validated against this guidance. 510K submission was developed based on these requirements. The required elements were reviewed during product development and testing. There were no deviations".

#### Intended Use of the Device (also see Indications for Use Statement):

The ORA Implant Abutment System is indicated for use with dental implants to support and/or retain removable dental prostheses in the treatment of partially or totally edentulous patients to restore chewing function. The abutment screws directly into endosseous implants or they screw into SFI Abutments which are screwed into endosseous implants.

Implant Brand	Model	
Nobel Biocare Brånemark System	3.3 Fixture, 3.75 Fixture, 4.0 Fixture, 5.0 Fixture (Old Version), 3.75 MkII Self-tapping Fixture, 4.0 MkII Self-tapping Fixture	
Sterngold-ImplaMed	3.3 Hex Cylinder, 4.0 Hex Cylinder, 3.75 Standard Hex Screw, 3.75 Self-tapping Hex Screw, 3.75 Self-tapping "SST" Hex Screw, 4.0 Standard Hex Screw, 4.0 Self-tapping "SST" Hex Screw, 3.75 RP Acid Etched, 4.0 RP Acid Etched, 5.0 RP Acid Etched, 4.1 Stern IC (4.8 head), 3.3 Stern IC (4.8 head)	
Nobel Biocare (Steri-Oss®)	3.8 HL Cylinder, 3.8 HL Threaded, 4.5 HL Threaded, 3.5 NobelReplace™, Replace® Select (NP), 4.0 NobelReplace Straight, (RP), 4.3Replace®Select&NobelReplace™ (RP)	
Keystone (Lifecore)	3.75 Restore® Self-tapping Screw, 4.0 Restore® Self-tapping Screw, 3.75 Restore® External Hex Screw, 4.0 Restore® External Hex Screw, 4.0 Restore® External Hex Cylinder, 4.2 Sustain® External Hex Cylinder, 3.75 Sustain® External Hex Screw, 4.0 Sustain® External Hex Screw, 4.2 Sustain® External Hex MC Cylinder, Stage-1TM (3.3 and 4.0 fixtures)	
3i Implant Inovations	3.25 External Hex Miniplant®, 3.25 ICE <sup>™</sup> Miniplant®, 3.25 OSSEOTITE® Miniplant®, 3.3 Cylinder Miniplant®, 3.3 External Hex Cylinder, 3.75 ICE <sup>™</sup> Self-tapping, 3.75 OSSEOTITE®, 3.75 Self-tapping Threaded, 3.75 Standard Threaded, 4.0 External Hex Cylinder, 4.0 ICE <sup>™</sup> Self-tapping, 4.0 OSSEOTITE®, 4.0 Standard Threaded, 4.25 External Hex Cylinder, TG OSSEOTITE® (4.8 Platform), 4.0 OSSEOTITE® Certain <sup>™</sup> , 4.0 OSSEOTITE® NTCertain <sup>™</sup> , 4.0 OSSEOTITE®CERTAIN PREVAIL, 5.0 Osseotite® Certain, 5.0 Osseotite® NT Certain, 5.0 Osseotite® Certain Prevail	
IMTEC Corporation®	3.3 Universal Flare Cylinder, 3.75 Universal Self-tapping, 3.75 Universal Self-tapping Coated, 4.0 Spike Cylinder, 4.0 Universal Cylinder	
Interpore IMZ <sup>TM</sup>	3.3 Hex Cylinder, 3.75 Self-tapping Threaded, 4.0 Hex Cylinder, 4.0 Self-tapping Threaded, 4.25 Hex Cylinder	
Osstem	4.1 US II, III, II Plus, III Plus, SS II, III (4.8 head)	

Zimmer Dental	3.5 Bio-Vent® X <sup>TM</sup> , 3.75 Swede-Vent <sup>TM</sup> Conical Neck CST, 3.75 Swede-Vent <sup>TM</sup> Standard, 4.0 Swede-Vent <sup>TM</sup> Standard, 4.0 Bio-Vent® X <sup>TM</sup> , 3.25 Micro-Vent® (3.5 head), 3.3 Screw-Vent® (3.5 head), 3.5 Bio-Vent® (3.5 head), 3.7 Screw-Vent® (3.5 head), 4.7 Screw-Vent® (3.5 head), 4.25 Micro-Vent® (4.5 head), 4.5 Bio-Vent® (4.5 head), 4.7 Screw-Vent® (4.5 head), 5.3 Core-Vent® (4.5 head), 3.7 Tapered Swiss Plus <sup>TM</sup> (4.8 platform), 4.8 Tapered Swiss Plus <sup>TM</sup> 4.1 Straight Swiss Plus <sup>TM</sup> , 4.8 Straight Swiss Plus <sup>TM</sup>	
Zimmer (Calcitek®, Centerpulse)	3.75 ThreadLoc <sup>IM</sup>	
Straumann	ITI TE <sup>™</sup> 3.3 (4.8 head), ITI 3.3 Std & Std Plus (4.8 head), ITI TE <sup>™</sup> 4.1 (4.8 head), ITI 4.1 Std. & Std. Plus (4.8 head), ITI, 4.8 Std. & Std. Plus (4.8 head)	
Biolok International	4.5 Silhouette Screw, 4.0 Micro-Lok Screw, 4.0 Micro-Lok Cylinder, 3.75 Micro-Lok Screw, 3.3 Micro-Lok Cylinder	
Bud	3.25 Bud Screwvent, 3.75 Bud Screwvent	
INNOVA	4.1 ENDOPORE® External Connection, 4.0 ENTEGRATM External Connection	
OIC	3.0 Osteo Standard ST, 3.25 Osteo Standard ST, 3.75 Osteo Standard ST	
MIS IMPLANTS	3.3mm Internal Hex, 3.75mm Internal Hex, 4.20mm Internal Hex, 5.0mm Internal Hex	
BioHorizons®	3.5 Internal, 4.0 Internal, 4.5 Internal, 3.5 Single Stage, 4.5 Single Stage	
Implant Direct	Legacy 3.5mm, Legacy 4.5mm, RePlant™ 4.3mm, RePlant™ 3.5mm, 3.7mm ScrewPlant, 4.7mm ScrewPlant	
Minimatic/Stryker	3.3 External Hex Cylinder, 3.75 External Hex Screw, 4.0 External Hex Cylinder, 4.0 External Hex Screw, 4.75 External Hex Screw, 5.0 External Hex Cylinder	
Straumann	Straumann Bone Level RC, Blue Sky Bio Square Taper RC	
Straumann	Straumann Bone Level NC, Blue Sky Bio Square Taper NC	
Ankylos	Ankylos	
Nobel Biocare	Nobel Replace WP, Nobel Replace Select WP, NobelSpeedy Replace WP, Implant Direct 5.0 RePlant, BlueSky Bio 5.0 Trilobe	
Nobel Biocare	Nobel Conical Connection RP	
Nobel Biocare	Nobel Conical Connection NP, Blue Sky Bio Max	
Astra Dental	Astra 4.5 / 5.0, Blue Sky Bio Conus 12 4.5 / 5.0	
Astra Dental	Astra 3.5 / 4.0, Blue Sky Bio Conus 12 3.5 / 4.0	
Zimmer Dental	Zimmer TSV 5.7mm, Implant Direct Legacy 5.7, BioHorizon 5.7	

#### **Device Description:**

- Design Characteristics See Attachment B
- Material composition—See Attachment B

#### **Sterilization Information:**

See Attachment F

#### **Labeling Information:**

See Attachment E

#### Mechanical Testing:

The applicable FDA guidance requires mechanical testing for implant or abutment designs that are significantly different from those of the predicate devices. As detailed in **Attachment C**, the proposed Stern IC Dental Implant System fall within the range of currently marketed, predicate dental endosseous implant products that have been cleared for marketing through the 510(k) Premarket Notification process. Therefore, mechanical testing is not necessary to establish substantial equivalence for the proposed devices.

#### **Corrosion Testing:**

The applicable FDA guidance requires corrosion testing for implant systems that include components fabricated from dissimilar metals. The proposed ORA Implant Abutments do not contain dissimilar metals; therefore, corrosion testing is not necessary to establish substantial equivalence for the proposed devices.

#### **Biocompatibility Testing:**

The applicable FDA guidance require biocompatibility testing when a new material is used that has not been identified in a predicate device. The ORA Implant Abutments are manufactured from standard raw materials that have been used extensively in other currently marketed dental implant systems (see **Attachment B**). Therefore, no additional biocompatibility testing is required to establish substantial equivalence. Patient Contact for the proposed device: Permanent ( $\geq$  30 days)

#### **Animal and Clinical Studies:**

The applicable FDA guidance's request animal and/or clinical studies if the implant diameter is less than 3.0mm, if the length is less than 7mm, and if the angulations of the abutment is greater than 30°, or if the design of the device is significantly different from that of other legally marketed devices. As detailed in **Attachments B** and **C**, the proposed ORA Implant Abutments fall well within the range of currently marketed, predicate devices that has been cleared for marketing through the 510(k) Premarket Notification process. Therefore, animal and/or clinical studies are not necessary to establish substantial equivalence for the proposed devices.

#### ATTACHMENT F

### PACKAGING, STERILIZATION AND PYROGENICITY

#### **SECTION 10**





#### **Pyrogenicity**

Like other currently marketed Sterngold dental implant products, the proposed ORA Implant Abutments are not labeled as non-pyrogenic.

#### **Expiration Dating**

Like other currently marketed Sterngold prosthetic products, the proposed ORA Implant Abutments do not have an expiration date. Device is supplied non-sterile.

# ATTACHMENT H INSTRUCTIONS FOR USE SECTION 12



23 Frank Mossberg Drive Attleboro, MA 02703 800.243.9942 • 508.226.5660 www.sterngold.com

#### **ORA Implant Abutments**

Instructions for Use Sterngold Dental

#### **ENGLISH**

Before using the ORA Implant Abutments, the clinician in charge should carefully study the indications, contraindications, recommendations, warnings and instructions, as well as all other product-specific information (technical product description, description of the surgical and restorative technique, catalogue sheet, etc.) and fully comply with them. Detailed instructions over and above those contained in these instructions for use can be found in the technical user's guide. It is also recommended to attend the appropriate user-training courses. The aforementioned documents and details of the training courses may be obtained from the appropriate representatives in the various countries. The manufacturer, the importer and the suppliers of the ORA Implant Abutments are not liable for complications, other negative effects or damages that might occur for reasons such as incorrect indications, unsuitable choice of material or handling thereof, unsuitable use or handling of the instruments, asepsis and so on. The clinician is responsible for any such complications or other consequences. It is also the clinician's responsibility to properly instruct and inform the patient on the functions, handling and necessary care of the product and on all known product risks.

#### INDICATIONS/INTENDED USE

The ORA Implant Abutment System is indicated for use with dental implants to support and/or retain removable dental prostheses in the treatment of partially or totally edentulous patients to restore chewing function. The abutment screws directly into endosseous implants or they screw into SFI Abutments which are screwed into endosseous implants.

The ORA Implant Abutments are compatible with the following implant systems:

Implant Brand	Model	
Nobel Biocare Brånemark System	MALI Colf tanning Fivture	
Sterngold-ImplaMed	3.3 Hex Cylinder, 4.0 Hex Cylinder, 3.75 Standard Hex Screw, 3.75 Self-tapping Hex Screw, 3.75 Self-tapping "SST" Hex Screw, 4.0 Self-tapping "SST" Hex Screw, 3.75 RP Acid Etched, 4.0 RP Acid Etched, 5.0 RP Acid Etched, 4.1 Stern IC (4.8 head), 3.3 Stern IC (4.8 head)	
Nobel Biocare (Steri-Oss®)	3.8 HL Cylinder, 3.8 HL Threaded, 4.5 HL Threaded, 3.5 NobelReplace™, Replace® Select (NP), 4.0 NobelReplace Straight, (RP), 4.3Replace®Select&NobelReplace™ (RP)	
Keystone (Lifecore)	3.75 Restore® Self-tapping Screw, 4.0 Restore® Self-tapping Screw, 3.75 Restore® External Hex Screw, 4.0 Restore® External Hex Cylinder, 4.2 Sustain® External Hex Cylinder, 3.75 Sustain® External Hex Screw, 4.0 Sustain® External Hex Screw, 4.2 Sustain® External Hex MC Cylinder, Stage-1TM (3.3 and 4.0 fixtures)	
3i Implant Inovations	3.25 External Hex Miniplant®, 3.25 ICE™ Miniplant®, 3.25 OSSEOTITE® Miniplant®, 3.3 Cylinder Miniplant®, 3.3 External Hex Cylinder, 3.75 ICE™ Self-tapping, 3.75 OSSEOTITE®, 3.75 Self-tapping Threaded, 3.75 Standard Threaded, 4.0 External Hex Cylinder, 4.0 ICE™ Self-tapping, 4.0 OSSEOTITE®, 4.0 Standard Threaded, 4.25 External Hex Cylinder, TG OSSEOTITE® (4.8 Platform), 4.0 OSSEOTITE® Certain™, 4.0 OSSEOTITE® NTCertain™, 4.0 OSSEOTITE® CERTAIN PREVAIL, 5.0 Osseotite® Certain, 5.0 Osseotite® NT Certain, 5.0 Osseotite®Certain Prevail	
IMTEC Corporation®	3.3 Universal Flare Cylinder, 3.75 Universal Self-tapping, 3.75 Universal Self-tapping Coated, 4.0	
Interpore IMZ <sup>TM</sup>	3.3 Hex Cylinder, 3.75 Self-tapping Threaded, 4.0 Hex Cylinder, 4.0 Self-tapping Threaded, 4.25 Hex Cylinder	
Osstem	4.1 US II, III, II Plus, III Plus, SS II, III (4.8 head)	

610371 Rev A

Zimmer Dental	3.5 Bio-Vent® X <sup>™</sup> , 3.75 Swede-Vent Conical Neck CS1, 3.75 Swede-Vent Standard, 4.5 Swede-Vent Standard, 4.0 Bio-Vent® X <sup>™</sup> , 3.25 Micro-Vent® (3.5 head), 3.3 Screw-Vent® (3.5 head), 4.3	
Records proc	head), 3.5 Bio-Vent® (3.5 head), 3.7 Screw-Vent® (3.5 head), 3.7 Screw-Vent® (3.5 head), 3.7 Screw-Vent® (4.5 head), 3.7 Screw-Vent® (4.5 head), 3.7 Tapered Swiss Plus (4.8 platform), 4.8 Tapered Swiss Plus 4.1 Straight Sw	
•	head). 5.3 Core-Vent® (4.5 head), 3.7 Tapered Swiss Plus (4.8 platform), 4.8 Tapered Swiss	
	Plus <sup>™</sup> 4.1 Straight Swiss Plus <sup>™</sup> , 4.8 Straight Swiss Plus <sup>™</sup>	
Zimmer (Calcitek®, Centerpulse)	3.75 ThreadLoc <sup>TM</sup>	
Straumann	ITI TE <sup>TM</sup> 3.3 (4.8 head), ITI 3.3 Std & Std Plus (4.8 head), ITI TE <sup>TM</sup> 4.1 (4.8 head), ITI 4.1 Std. & Std.	
	Plus (4.8 head), ITI, 4.8 Std. & Std. Plus (4.8 head)	
Biolok International	4.5 Silhouette Screw, 4.0 Micro-Lok Screw, 4.0 Micro-Lok Cylinder, 3.75 Micro-Lok Screw, 3.3	
	Micro-Lok Cylinder	
Bud	3.25 Bud Screwvent, 3.75 Bud Screwvent	
4.1 ENDOPORE® External Connection, 4.0 ENTEGRATM External Connection		
2.0 Osteo Standard ST 3.25 Osteo Standard ST 3.75 Osteo Standard ST		
2 2mm Internal Hey 3 75mm Internal Hex, 4,20mm Internal Hex, 5,00mm Internal Hex, 5,00mm Internal Hex		
BioHorizons®	3.5 Internal, 4.0 Internal, 4.5 Internal, 3.5 Single Stage, 4.5 Single Stage	
Implant Direct	3.5 Internal, 4.0 Internal, 4.5 Internal, 3.5 Single Glage, 4.5 S	
	ScrewPlant 10 External Hex Cylinder 4 0 External Hex	
Minimatic/Stryker	3.3 External Hex Cylinder, 3.75 External Hex Screw, 4.0 External Hex Cylinder, 4.0 External Hex	
TVIII II	Screw, 4.75 External Hex Screw, 5.0 External Hex Cylinder	
Straumann	Straumann Bone Level RC, Blue Sky Bio Square Taper RC	
Straumann	Straumann Bone Level NC, Blue Sky Bio Square Taper NC	
Ottomium		
Nobel Biocare	Ankylos   Nobel Replace WP, Nobel Replace Select WP, NobelSpeedy Replace WP, Implant Direct 5.0	
14000, 5100310	RePlant, BlueSky Bio 5.0 Trilobe	
Nobel Biocare	Nobel Conical Connection RP	
Nobel Biocare	Nobel Conical Connection NP, Blue Sky Bio Max	
Astro Pontal Astra 4.5 / 5.0. Blue Sky Bio Conus 12 4.5 / 5.0		
Astra 3 5 / 4 0 Blue Sky Bio Conus 12 3.5 / 4.0		
Zimmer Dental Zimmer TSV 5.7mm, Implant Direct Legacy 5.7, BioHorizon 5.7		

#### CONTRAINDICATIONS

The ORA Implant Abutments can only be screwed into compatible Implant. They should not be used by anyone with allergies or hypersensitivity to titanium alloy, Ti 6Al 4V.

#### WARNINGS

The ORA Implant Abutments should not be used unless the dental implants are stable and there are no signs of infection or severe bone loss. Poor bone quality, poor patient oral hygiene, heavy tobacco use, uncontrolled systemic diseases (diabetes, etc.), reduced immunity, alcoholism, drug addiction, and psychological instability may contribute to lack of integration and/or subsequent implant failure. Severe bruxism, clenching, and overloading may cause bone loss, screw loosening, component fracture, and/or implant failure. Exposure to radiation and chemotherapy may impact health of the implant. Dental implant patients should be instructed to consult with their physician prior to undergoing such treatment options.

Restorative techniques required to place and restore dental implants are highly specialized and complex procedures. Practitioners should attend courses of study to familiarize themselves with implantology techniques. Improper technique can cause bone loss and implant failure.

Other relative contraindications include steroid and anticoagulant treatment which may affect the surgical site, surrounding tissue, or patient's healing function. Exposure to long-term use of bisphosphonate drugs especially with chemotherapy may impact implant survival. Careful patient selection including consultation with the attending physician is strongly recommended prior to implant treatment. Excessive mobility, bone loss, or infection may indicate the implant is failing. Any implant which appears to be failing should be treated or removed as soon as possible. If removal is necessary, curette any soft tissue from the implant site and allow site to heal as though it were an atraumatic extraction. Due to the metal conductivity, electrosurgery around the implants and intraoral abutment preparations without irrigation could result in tissue damage and implant failure. Patients should consult with their physician and imaging technician prior to undergoing an MRI procedure.

#### PRECAUTIONS

Proper case planning is essential to the long-term success of both the prostheses and the implants. Overload is one of the key contributors to implant failure. Ensure the implant angle corrections are appropriate for the occlusal load.

Implant fractures can occur when applied loads exceed the normal functional design tolerances of the implant components. Potential overloading conditions may result from deficiencies in implant numbers, lengths and/or diameters to adequately support a restoration, excessive cantilever length, incomplete abutment seating, abutment angles greater than 30 degrees, occlusal interferences causing excessive lateral forces, patient parafunction (e.g. bruxing, clenching), improper denture manufacture procedures, inadequate denture fit, and physical trauma.

It is the responsibility of the clinician to instruct the patient on all appropriate contraindications, side effects, and precautions as well as the need to seek the services of a trained dental professional if there are any changes in the performance of the implant (e.g., looseness of the prosthesis, infection or exudate around the implant, pain, or any other unusual symptoms that the patient has not been told to expect).

Long-term implant health is directly related to the maintenance of oral hygiene. Potential implant candidates should establish an adequate oral hygiene regimen prior to implant therapy. Following implant placement, the clinician should instruct the patient on proper tools and techniques to ensure long-term maintenance of the implant(s). The patient should also be instructed to maintain routinely scheduled prophylaxis and evaluation appointments.

610371 Rev A

**General Considerations** 

Control of biomechanical stresses is the key factor to long-term success of the prosthesis. Even after implant integration, imbalances in occlusal forces can lead to implant failure. Implant patients should be monitored for signs of peri-implant bone loss and excessive attachment wear as signs of occlusal overloading.

**ADVERSE EFFECTS** 

The following complications may occur relative to implant placement: pain, discomfort, dehiscence, delayed healing, paresthesia, hyperesthesia, edema, hemorrhage, hematoma, infection, inflammation, local and generalized allergic reaction, lack of integration, loss of bone, and loss of implant. Other adverse effects may also occur as a result of iatrogenic factors and host responses.

Single Use

Reuse of a single use device that has come in contact with blood, bone, tissue or other body fluids may lead to patient or user injury. Possible risks associated with reuse of a single use device include, but are not limited to, mechanical failure and transmission of infectious agents.

**Product Packaging** 

ORA Implant Abutments are packaged in a sealed chevron pouch. These pouches are not autoclavable. Parts need to be removed from pouch prior to autoclaving and placed in an autoclavable pouch or tray.

#### **CLEANING/STERILIZATION INFORMATION**

Sterngold Dental prosthetic and ancillary components are sold non-sterile. Sterilize or disinfect according to the procedures below prior to use in patients.

The autoclave is to be used according to manufacturer instructions. The health care facility should monitor the sterilizer for the facility according to an FDA recognized sterility assurance standard such as ANSI/AAMI ST79.

Disinfection and sterilization procedures should conform to OSHA or local guidelines for blood borne pathogens.

Non Sterile Abutments shall be sterilized using steam sterilization and a gravity placement autoclave. The following sterilization parameters (method, time, and temperature) are required to achieve a 10-6 sterility assurance level (SAL). Local or national specifications should be followed where steam sterilization requirements are stricter or more conservative than those listed below.

Cleaning

Use the following guidelines for cleaning products:

Rinse with cool-to-lukewarm water for two-and-one-half minutes. For all parts place in an ultrasonic cleaner with an enzymatic detergent diluted with tap water per the manufacture's guidelines. Sonicate for 10 minutes. Rinse with tap water for three minutes.

Sterilization

Individual parts shall be placed in appropriate autoclave using steam sterilization. The following sterilization parameters (method, time, and temperature) are required to achieve a 10-6 sterility assurance level (SAL).

To ensure autoclave is performing effectively, periodic use of biologic indicators should be considered.

Cycle Type: Steam Sterilization Temperature: 121°C / 250°F Exposure Time: 40 minutes Dry Time: 15 - 30 minutes

**Operation Mechanism** 

Choose the abutment with the proper cuff height that fits the existing implant or choose the ORA Abutment that will screw into an SFI Abutment. Screw an abutment into each implant or SFI Abutment. The abutments are tightened to 20 Ncm, using a hex tool which engages the hex at the base of the ball.

Once the O-Ring Abutments are in place, an impression is taken using a light impression material. Impression is sent to the laboratory so that the denture can be created.

The O-Ring Abutments can remain in place while the denture is being created.

The laboratory will incorporate the O-Ring Retainers into the denture. After the material has cured, the denture is removed. The red o-ring is pulled out of the metal housing and the white o-ring is inserted into its place.

The denture is then snapped onto the ball abutment in the patient's mouth.

O-Ring Placement Procedure:

The retaining ring (metal housing) comes with the red o-ring (which is a firm rubber) inside. The retaining ring (metal housing) with the red o-ring is pushed over the wide part of the ball until seated. The stiffness of the red o-ring holds the housing in position. Any exposed areas of the abutment are blocked out so that only the metal housing is exposed. The retaining ring (metal housing) is then processed into the denture. After the material has cured, the denture is removed. The red o-ring is pulled out of the metal housing and the white o-ring is inserted into its place. The white o-ring is more flexible making insertion and removal easier.

MR Safety: The ORA Implant Abutments are manufactured from a non-ferromagnetic material: 6AL-4V ELI titanium.

Titanium is usually recommended for long term implantable devices because it is safe and completely non-magnetic, non-electrically conductive and non-RF reactive eliminating all of the primary potential threats during an MRI procedure.

The ORA Implant Abutments have not been evaluated for safety and compatibility in the MR environment. The ORA Implant Abutments have not been tested for heating or migration in the MR environment.

The proposed devices do not contain or utilize software.

610371 Rev A

Manufactured and Distributed by CDRH on 09-06-2016 Sterngold Dental, LLC 23 Frank Mossberg Drive Attleboro, MA 02703-0967 USA 1-800-243-9942 or 508-226-5660

European Representative: Federico Perex San Prudencio 25 Vitoria 01005 Spain

Ph: +34 945 230 736 Fax: +34 945 230 236

Label Symbol	Used For	Symbol	Used For
	Do not reuse	NON STERILE	Symbol for Non- Sterile
REF	Catalog number	LOT	Batch code
	Manufacturer	$\triangle$	Caution, consult accompanying documents
Ronly	Symbol for "Use by Prescription only"	CE	Symbol for "European Conformity"
EC REP	Authorized representative in the European Community		

### **ATTACHMENT I**

**510 (k) Summary** 

**SECTION 13** 

#### 510(k) Summary

Sponsor:

Sterngold Dental, LLC 23 Frank Mossberg Drive

Attleboro, MA 02703

Contact:

Maria Rao, QA/RA Director

Ph: 508-226-5660 ext 1206

Trade Name:

**ORA** Implant Abutments

Common Name:

Implant Abutments

Classification Name: Endosseous Dental Implant Abutment

Classification:

According to Section 513 of the Federal Food, Drug, and

Cosmetic Act, the device classification is Class II

**Product Code:** 

NHA (21CFR 872.3630)

Legally Marketed Device to which Equivalence is claimed (Predicate Devices):

Predicate Device(s): K900099, K130183.

K900099

The O-Ring System – ORS

K130183

SFI Bar® Implant Abutments for 7 Platforms

**Description of Device:** 

The ORA Implant Abutment is a precision machined ball shaped abutment that connects a compatible dental implant system with a removable partial or complete overdenture. The implant abutment is screwed into the dental implant. Connection to and retention of a denture is provided by a rubber o-ring, which may or may not be held within a metal housing. There are two color o-rings, a red processing o-ring and a white final o-ring.

The retaining ring (metal housing) comes with the red o-ring (which is a firm rubber) inside. The retaining ring (metal housing) with the red o-ring is pushed over the wide part of the ball until seated. The stiffness of the red o-ring holds the housing in position. Any exposed areas of the abutment are blocked out so that only the metal housing is exposed. The retaining ring (metal housing) is then processed into the denture. After the material has cured, the denture is removed. The red o-ring is pulled out of the metal housing and the white o-ring is inserted into its place. The white o-ring is more flexible making insertion and removal easier.

The bottom portion of the abutment (cuff area to end of threads) is an exact replica of the SFI Implant Abutments previously cleared by K130183.

ORA Implant Abutments are available in sixteen different platforms and each platform is compatible with one or more implant types. Table 1 demonstrates implant/abutment compatibility. The difference between each platform is the internal connection with the specific implant. This connection has been previously cleared by K130183 – SFI Abutments.

The devices are supplied non-sterile, and there is no shelf life.



#### Intended Use of the Device:

The ORA Implant Abutment System is indicated for use with dental implants to support and/or retain removable dental prostheses in the treatment of partially or totally edentulous patients to restore chewing function. The abutment screws directly into endosseous implants or they screw into SFI Abutments which are screwed into endosseous implants.

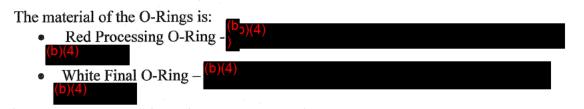
Implant Brand	Model		
Nobel Biocare Brånemark System	3.3 Fixture, 3.75 Fixture, 4.0 Fixture, 5.0 Fixture (Old Version), 3.75 MkII Self-tapping Fixture, 4.0 MkII Self-tapping Fixture		
Sterngold-ImplaMed	3.3 Hex Cylinder, 4.0 Hex Cylinder, 3.75 Standard Hex Screw, 3.75 Self-tapping Hex Screw, 3.75 Self-tapping "SST" Hex Screw, 4.0 Standard Hex Screw, 4.0 Self-tapping "SST" Hex Screw, 5.0 RP "SST" Hex Screw, 3.75 RP Acid Etched, 4.0 RP Acid Etched, 5.0 RP Acid Etched, 4.1 Stern IC (4.8 head), 3.3 Stern IC (4.8 head)		
Nobel Biocare (Steri-Oss®)	3.8 HL Cylinder, 3.8 HL Threaded, 4.5 HL Threaded, 3.5 NobelReplace™, Replace® Select (NP), 4.0 NobelReplace Straight, (RP), 4.3Replace®Select&NobelReplace™ (RP)		
Keystone (Lifecore)	3.75 Restore® Self-tapping Screw, 4.0 Restore® Self-tapping Screw, 3.75 Restore® External Hex Screw, 4.0 Restore® External Hex Cylinder, 4.2 Sustain® External Hex Cylinder, 3.75 Sustain® External Hex Screw, 4.0 Sustain® External Hex Screw, 4.2 Sustain® External Hex MC Cylinder, Stage-1TM (3.3 and 4.0 fixtures)		
3i Implant Inovations	3.25 External Hex Miniplant®, 3.25 ICE <sup>™</sup> Miniplant®, 3.25 OSSEOTITE® Miniplant®, 3.3 Cylinder Miniplant®, 3.3 External Hex Cylinder, 3.75 ICE <sup>™</sup> Self-tapping, 3.75 OSSEOTITE®, 3.75 Self-tapping Threaded, 3.75 Standard Threaded, 4.0 External Hex Cylinder, 4.0 ICE <sup>™</sup> Self-tapping, 4.0 OSSEOTITE®, 4.0 Standard Threaded, 4.25 External Hex Cylinder, TG OSSEOTITE® (4.8 Platform), 4.0 OSSEOTITE® Certain <sup>™</sup> , 4.0 OSSEOTITE® NTCertain <sup>™</sup> , 4.0 OSSEOTITE® CERTAIN PREVAIL, 5.0 Osseotite® Certain, 5.0 Osseotite® NT Certain, 5.0		
IMTEC Corporation®	Osseotite®Certain Prevail  3.3 Universal Flare Cylinder, 3.75 Universal Self-tapping, 3.75 Universal Self-tapping Coated, 4.0  Spike Cylinder, 4.0 Universal Cylinder		

Interpore IMZ <sup>TM</sup>	3.3 Hex Cylinder, 3.75 Self-tapping Threaded, 4.0 Hex Cylinder, 4.0 Self-tapping Threaded, 4.25 Hex	
	Cylinder	
Osstem	4.1 US II, III, II Plus, III Plus, SS II, III (4.8 head)	
Zimmer Dental	3.5 Bio-Vent® X <sup>IM</sup> , 3.75 Swede-Vent <sup>IM</sup> Conical Neck CST, 3.75 Swede-Vent <sup>IM</sup> Standard, 4.0 Swede-Vent <sup>IM</sup> Standard, 4.0 Bio-Vent® X <sup>IM</sup> , 3.25 Micro-Vent® (3.5 head), 3.3 Screw-Vent® (3.5 head), 3.5 Bio-Vent® (3.5 head), 3.7 Screw-Vent® (3.5 head), 3.75 Screw-Vent® (3.5 head), 4.3 Core-Vent® (3.5 head), 4.25 Micro-Vent® (4.5 head), 4.5 Bio-Vent® (4.5 head), 4.7 Screw-Vent® (4.5 head), 5.3 Core-Vent® (4.5 head), 3.7 Tapered Swiss Plus <sup>TM</sup> (4.8 platform), 4.8 Tapered Swiss Plus <sup>TM</sup> 4.1 Straight Swiss Plus <sup>TM</sup> , 4.8 Straight Swiss Plus <sup>TM</sup>	
Zimmer (Calcitek®, Centerpulse)	3.75 ThreadLoc <sup>1M</sup>	
Straumann	ITI TE <sup>™</sup> 3.3 (4.8 head), ITI 3.3 Std & Std Plus (4.8 head), ITI TE <sup>™</sup> 4.1 (4.8 head), ITI 4.1 Std. & Std. Plus (4.8 head), ITI, 4.8 Std. & Std. Plus (4.8 head)	
Biolok International	4.5 Silhouette Screw, 4.0 Micro-Lok Screw, 4.0 Micro-Lok Cylinder, 3.75 Micro-Lok Screw, 3.3 Micro-Lok Cylinder	
Bud	3.25 Bud Screwvent, 3.75 Bud Screwvent	
INNOVA	4.1 ENDOPORE® External Connection, 4.0 ENTEGRATM External Connection	
OIC	3.0 Osteo Standard ST, 3.25 Osteo Standard ST, 3.75 Osteo Standard ST	
MIS IMPLANTS	3.3mm Internal Hex, 3.75mm Internal Hex, 4.20mm Internal Hex, 5.0mm Internal Hex	
BioHorizons®	3.5 Internal, 4.0 Internal, 4.5 Internal, 3.5 Single Stage, 4.5 Single Stage	
Implant Direct	Legacy 3.5mm, Legacy 4.5mm, RePlant™ 4.3mm, RePlant™ 3.5mm, 3.7mm ScrewPlant, 4.7mm ScrewPlant	
Minimatic/Stryker	3.3 External Hex Cylinder, 3.75 External Hex Screw, 4.0 External Hex Cylinder, 4.0 External Hex Screw, 4.75 External Hex Screw, 5.0 External Hex Cylinder	
Straumann	Straumann Bone Level RC, Blue Sky Bio Square Taper RC	
Straumann	Straumann Bone Level NC, Blue Sky Bio Square Taper NC	
Ankylos	Ankylos	
Nobel Biocare	Nobel Replace WP, Nobel Replace Select WP, NobelSpeedy Replace WP, Implant Direct 5.0 RePlant, BlueSky Bio 5.0 Trilobe	
Nobel Biocare	Nobel Conical Connection RP	
Nobel Biocare	Nobel Conical Connection NP, Blue Sky Bio Max	
Astra Dental	Astra 4.5 / 5.0, Blue Sky Bio Conus 12 4.5 / 5.0	
Astra Dental	Astra 3.5 / 4.0, Blue Sky Bio Conus 12 3.5 / 4.0	
Zimmer Dental	Zimmer TSV 5.7mm, Implant Direct Legacy 5.7, BioHorizon 5.7	

#### **Summary Technological Characteristics:**

The proposed implant abutments are substantially equivalent to the currently marketed predicate devices. The intended use, basic design, fundamental operating principles and manufacturing procedures are the same as the predicate devices.

The material of the implant abutments conform to ASTM F136, Wrought Titanium 6 Aluminum-4 Vanadium ELI Alloy.



# Comparison/Compatibility Substantial Equivalence:

The proposed implant abutments are substantially equivalent to the currently marketed predicate devices. The intended use, basic design, fundamental operating principles and manufacturing procedures are the same as the predicate devices.

To ensure compatibility the following process was carried out: The implant abutments were designed and developed, and manufactured according to manufacturer's specifications and controlled procedures. A validation protocol was done in accordance with Design Control requirements per FDA CFR820.30.

Table 2 summarizes the substantial equivalence comparison to the predicate devices.

#### Performance Data:

Application and functional testing have been conducted to evaluate the performance characteristics of the ORA Implant Abutments. The test methods used were the same as in predicate devices. Testing has shown that the ORA Implant Abutments included in this application are equivalent in performance characteristics to its predicate devices. The acceptance criteria were met. Refer to Test Report.

# Summary of Testing to Demonstrate Safety and Effectiveness / Conclusion:

Non-clinical test data was used to support the substantially equivalence claim. Clinical testing was not necessary. The non-clinical testing consisted of tolerance analysis of platforms to identify worst case test samples. Fatigue testing was not done as the basic design is the same as the predicate devices. The evaluation was based on FDA guidance "Class II Special Controls Guidance Document: Root-Form Endosseous Dental Implants and Endosseous Dental Implant Abutments." (b)(4) tests, application and functional tests have been carried out.

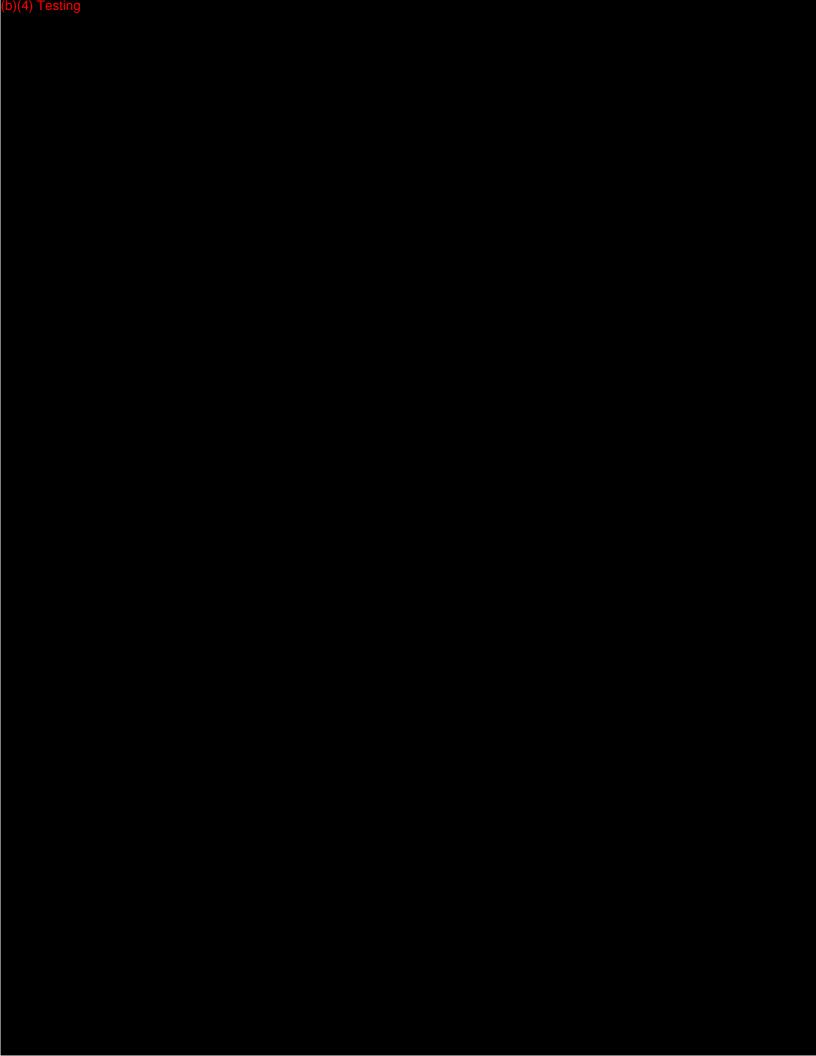
The summary of technological characteristics as well as application and functional testing indicate that the device is safe and effective for its intended use and performs as well or better than the predicate devices.

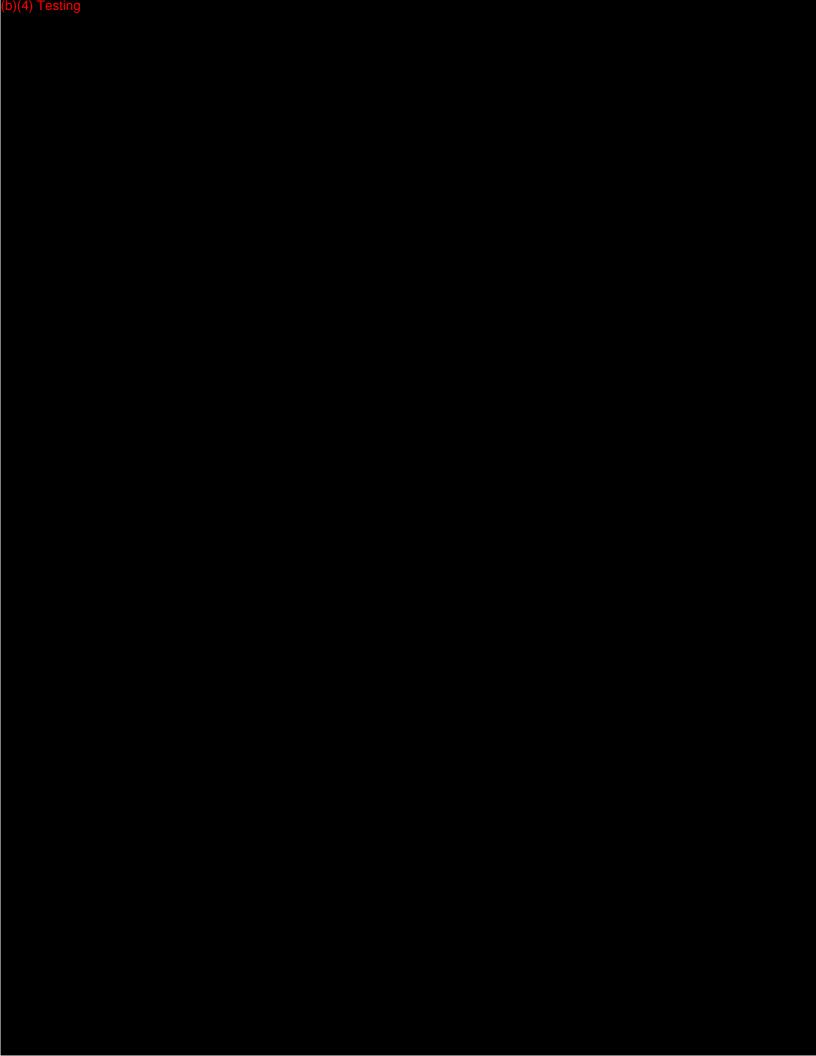


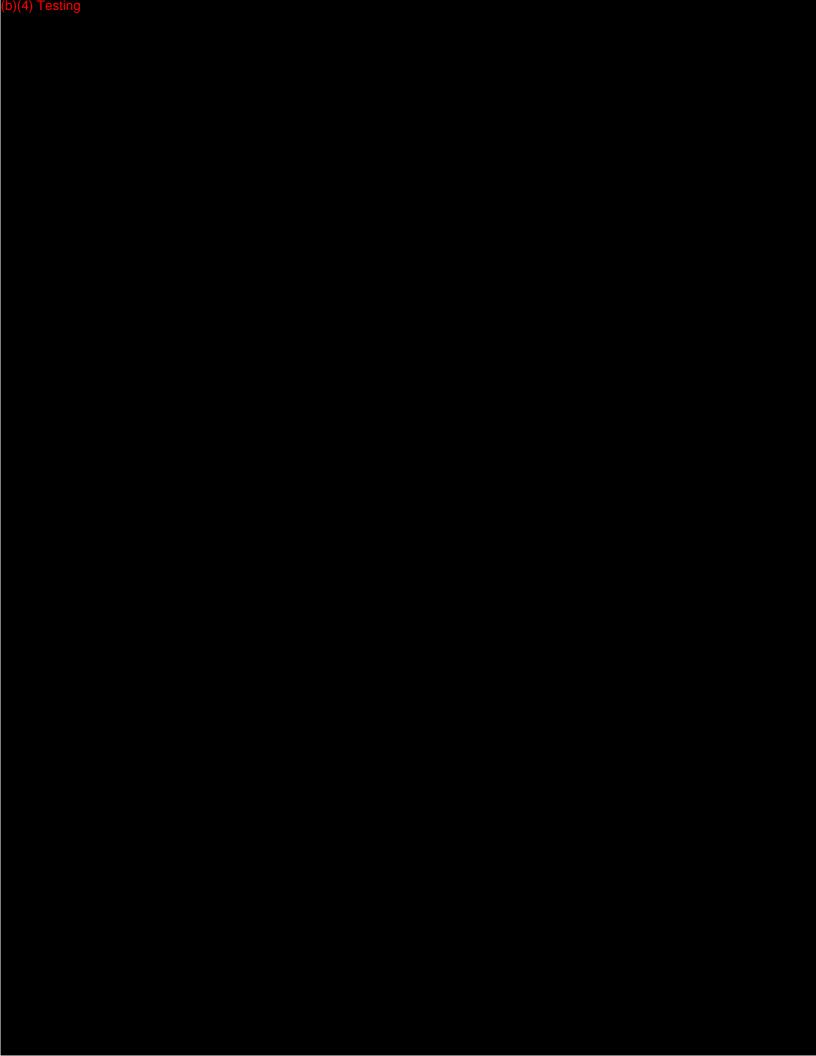
**TEST REPORT** 

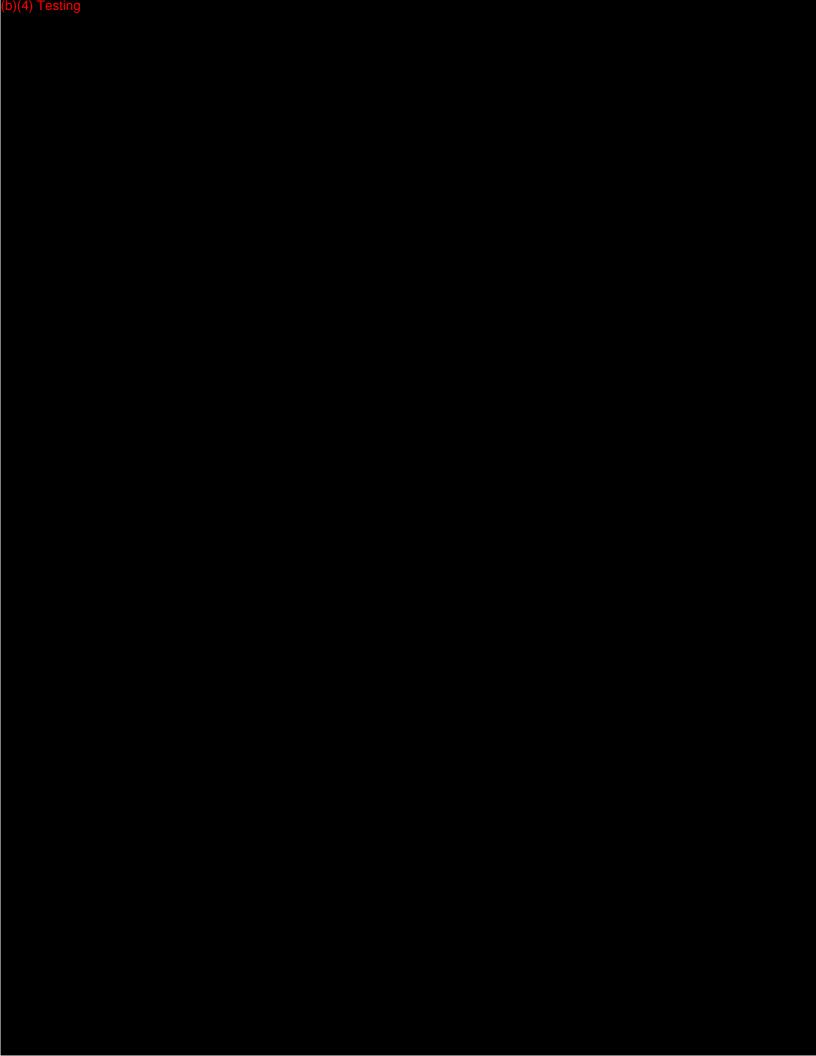
(b)(6)		
-		
Quality Manager		
(b)(6)		
Director of Regulatory Amairs		
(b)(6)	ı	
Design Engineer		

Date: <u>VOV 15, 2013</u>









#### Addendum to Product Information - Section F of Form FDA 3514

Records processed under FOIA Request # 2016-1128; Released by CDRH on 09-06-2016

Trade or Proprietary or Model Name of Device	Model Number
ORA 1.25MM [A]	904335
ORA 2.0MM [A]	
ORA 3.0MM [A]	904336
ORA 4.0MM [A]	904337
	904338
ORA 5.0MM [A] ORA 1.0MM [B]	904339
	904340
ORA 2.0MM [B]	904341
ORA 3.0MM [B]	904342
ORA 4.0MM [B]	904343
ORA 5.0MM [B]	904344
ORA 1.0MM [C]	904345
ORA 2.0MM [C]	904346
ORA 3.0MM [C]	904347
ORA 4.0MM [C]	904348
ORA 5.0MM [C]	904349
ORA 1.0MM [T]	904374
ORA 2.0MM [T]	904375
ORA 3.0MM [T]	904376
ORA 4.0MM [T]	904377
ORA 5.0MM [T]	904378
ORA 1.0MM [X]	904390
ORA 2.0MM [X]	904391
ORA 3.0MM [X]	904392
ORA 4.0MM [X]	904393
ORA 5.0MM [X]	904394
ORA 1.0MM [Z]	904464
ORA 2.0MM [Z]	904465
ORA 3.0MM [Z]	904466
ORA 4.0MM [Z]	904467
ORA 5.0MM [Z]	904468
ORA 1.0MM [BD]	904469
ORA 2.0MM [BD]	904470
ORA 3.0MM [BD]	904471
ORA 4.0MM [BD]	904472
ORA 5.0MM [BD]	904474
ORA 1.0MM [BE]	904550
ORA 2.0MM [BE]	904551
ORA 3.0MM [BE]	904552
ORA 4.0MM [BE]	904553
ORA 5.0MM [BE]	904554
ORA 1.0MM [AE]	904555
ORA 2.0MM [AE]	904556
ORA 3.0MM [AE]	904557
ORA 4.0MM [AE]	904558
ORA 5.0MM [AE]	904559

## Addendum to Product Information - Section F of Form FDA 3514

Trade or Proprietary or Model Name of Device | Model Number **Model Number** ORA 1.0MM [AN] 904670 ORA 2.0MM [AN] 904671 ORA 3.0MM [AN] 904672 ORA 4.0MM [AN] 904673 ORA 5.0MM [AN] 904674 ORA 1.0MM [AP] 904675 ORA 2.0MM [AP] 904676 ORA 3.0MM [AP] 904677 ORA 4.0MM [AP] 904678 ORA 5.0MM [AP] 904679 ORA 1.0MM [AY] 904680 ORA 2.0MM [AY] 904681 ORA 3.0MM [AY] 904682 ORA 4.0MM [AY] 904683 ORA 5.0MM [AY] 904684 ORA 1.0MM [AJ] 904685 ORA 2.0MM [AJ] 904686 ORA 3.0MM [AJ] 904687 ORA 4.0MM [AJ] 904688 ORA 5.0MM [AJ] 904689 ORA 1.0MM [AK] 904690 ORA 2.0MM [AK] 904691 ORA 3.0MM [AK] 904692 ORA 4.0MM [AK] 904693 ORA 5.0MM [AK] 904694 ORA 1.0MM [BF] 904695 ORA 2.0MM [BF] 904696 ORA 3.0MM [BF] 904697 ORA 4.0MM [BF] 904698 ORA 5.0MM [BF] 904699 **ORA Retaining Ring** 914065 Red Processing )-Ring 909011 White Final O-Ring 909012



Tel: (508) 226-5660 Cust. Serv: (800) 243-9942

Fax: (508) 226-5473

33791/SOOZ

Toll Free Fax: (800) 531-2685

23 Frank Mossberg Drive · Attleboro, MA 02703 http://www.sterngold.com

Alloys Attachments Implants Restorative Systems

FDA CDRH DMC

MAR 1 9 2014

Received

**ECOPY COVER LETTER** 

March 17, 2014

U.S. Food and Drug Administration Center for Devices and Radiological Health Document Mail Center-W066-0609 10903 New Hampshire Avenue Silver Spring, MD 20993-0002

RE: Abbreviated 510(k) Premarket Notification ORA Implant Abutment System – K133791

I am providing one replacement eCopy on CD containing seventeen (9) PDF files numbered as 001 - 009.

The eCopy is an exact duplicate of the paper copy being submitted.

Should you have any questions, please contact me at 508.226.5660 ext: 1206.

Sincerely,

Maria Rao

Director of Regulatory Affairs

Sterngold Dental LLC

2



Tel: (508) 226-5660

Cust. Serv: (800) 243-9942

Fax: (508) 226-5473 Toll Free Fax: (800) 531-2685

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Alloys Attachments Implants Restorative Systems

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The eCopy is an exact duplicate of the paper copy being submitted.

Should you have any questions, please contact me at 508.226.5660 ext: 1206.

Sincerely,

Maria Rao

**Director of Regulatory Affairs** 

Sterngold Dental LLC

#### Records processed under FOIA Request # 2016-1128; Released by CDRH on 09-06-2016



To:

"Giles, Lauren" <Lauren.Giles@fda.hhs.gov>,

Co:

Bcc:

Subject:

Re: ADDITIONAL INFORMATION REQUESTED FOR K133791, ORA Implant Abutment

System

#### SEE BELOW:

Maria Rao Director of Quality & Regulatory Affairs Sterngold Dental, LLC phone 508-226-5660 X 1206

"Giles, Lauren"

To: Maria Rao

Sterngold Dental Llc

03/13/2014 05:42:07 PM

From:

"Giles, Lauren" < Lauren. Giles@fda.hhs.gov>

To:

"maria.rao@sterngold.com" <maria.rao@sterngold.com>,

Date:

03/13/2014 05:42 PM

Subject:

ADDITIONAL INFORMATION REQUESTED FOR K133791, ORA Implant Abutment System

To:

Maria Rao

Sterngold Dental Llc

Phone: Sterngold Dental Llc

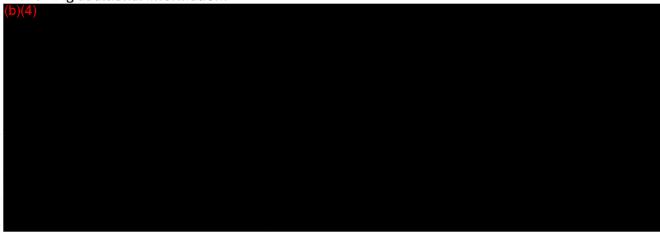
E-Mail: maria.rao@sterngold.com

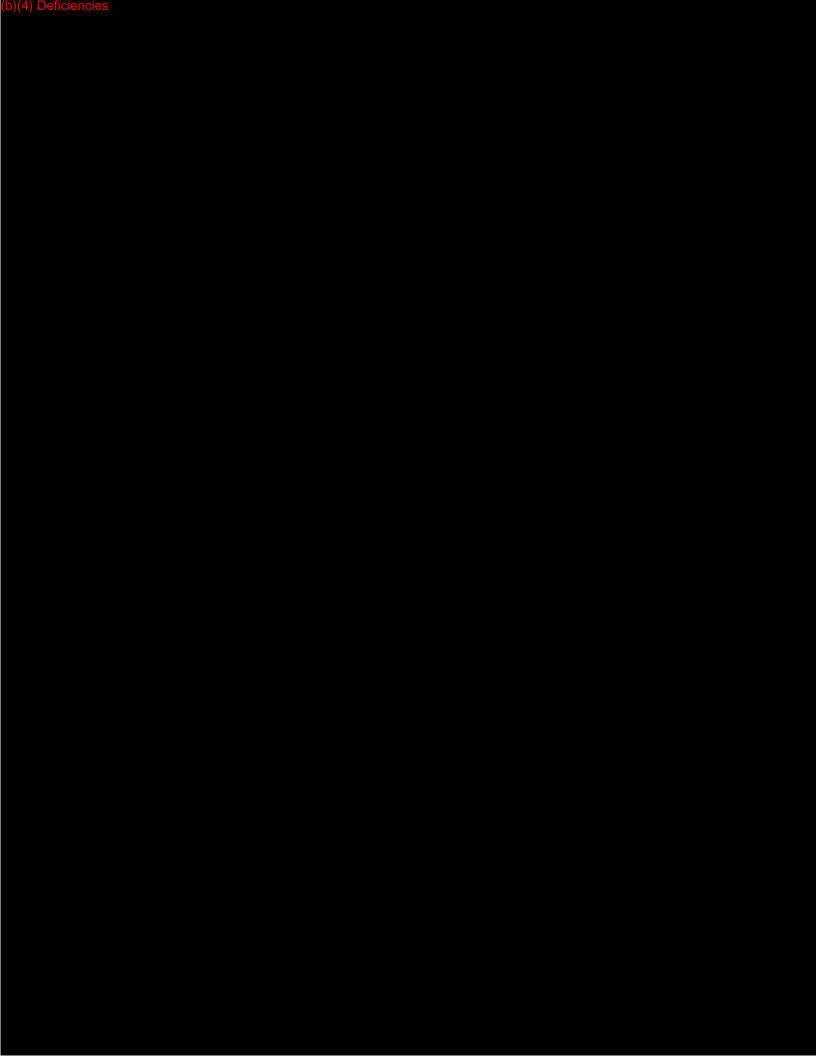
Subject: Additional information requested / Telephone hold for K133791 ORA Implant

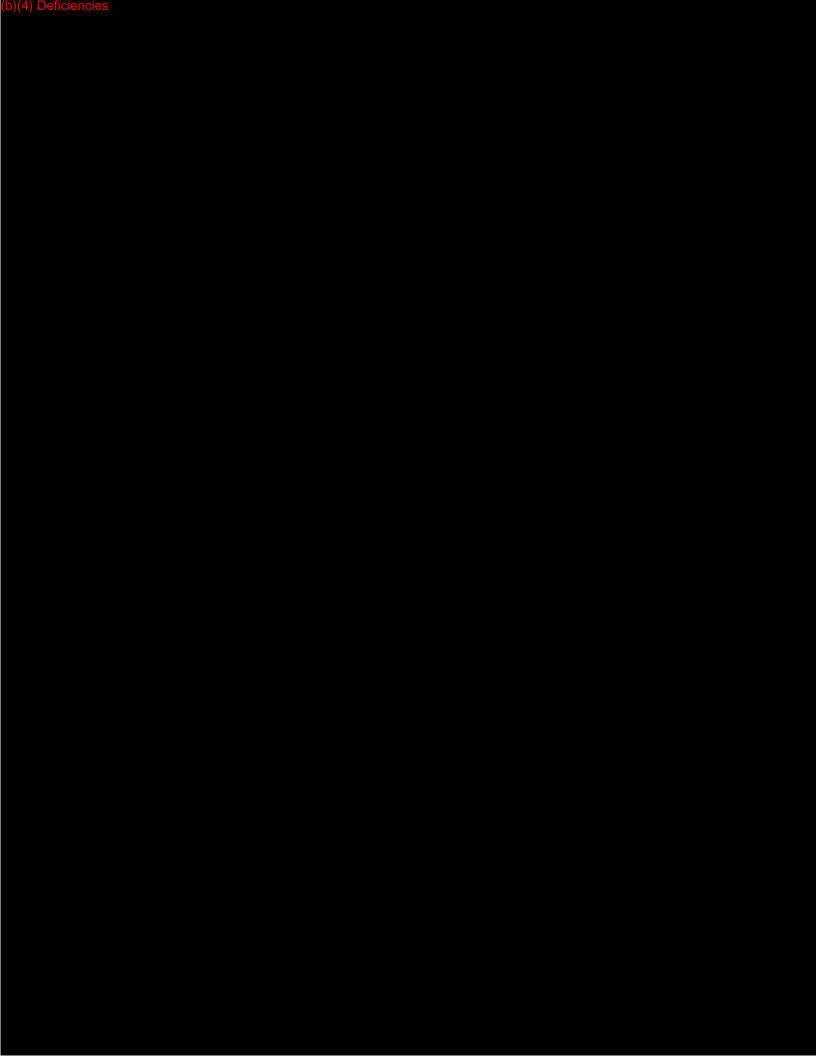
**Abutment System** 

CC: Record

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. This 510(k) will be placed on telephone hold. To complete the review of your submission, we require the following additional information:









The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act (Act) for determining substantial equivalence of your device.

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(I), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Act. You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations (21 CFR 812).

In accordance with 21 CFR 807.87(I), FDA may consider a 510(k) to be withdrawn if the submitter fails to provide additional information within 30 days of an Additional Information (AI) request. FDA generally permits submitters additional time to respond to such requests. FDA intends to automatically grant a maximum of 180 calendar days from the date of the AI request, even if the submitter has not requested an extension. Therefore, submitters are no longer required to submit written requests for extension. However, you should be aware that FDA intends to issue a notice of withdrawal under 21 CFR 807.87(I) if FDA does not receive, in a submission to the appropriate Document Control Center, a complete response to all of the deficiencies in this AI request within 180 calendar days of the date of this request. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission

### **DEVICE DESCRIPTION**

This Abbreviated 510(k) Premarket Notification seeks clearance for the ORA Implant Abutments.

The ORA Implant Abutment System is a precision machined ball shaped abutment that connects a compatible dental implant system with a removable partial or complete overdenture. The implant abutment is screwed into the dental implant. Connection to and retention of a denture is provided by a rubber o-ring, which may or may not be held within a metal housing. There are two color o-rings, a red processing o-ring and a white final o-ring.

The retaining ring (metal housing) comes with the red o-ring (which is a firm rubber) inside. The retaining ring (metal housing) with the red o-ring is pushed over the wide part of the ball until seated. The stiffness of the red o-ring holds the housing in position. Any exposed areas of the abutment are blocked out so that only the metal housing is exposed. The retaining ring (metal housing) is then processed into the denture. After the material has cured, the denture is removed. The red o-ring is pulled out of the metal housing and the white o-ring is inserted into its place. The white o-ring is more flexible making insertion and removal easier. This procedure can be done in the laboratory or in the dentist's office.

The bottom portion of the ORA abutment (cuff area to end of threads) is an exact replica of the SFI Implant Abutments previously cleared by K130183.

The ORA Implant Abutment System is available in sixteen different platforms and each platform is compatible with one or more implant types. Table 1 demonstrates implant/abutment compatibility. The difference between each platform is the internal connection with the specific implant. This connection has been previously cleared by K130183 and K132814– SFI Implant Abutments.

Implant Brand	Model		
Straumann [BD]	Straumann Bone Level RC, Blue Sky Bio Square Taper RC		
Straumann [BE]	Straumann Bone Level NC, Blue Sky Bio Square Taper NC		
Ankylos [AE]	Ankylos		
Nobel Biocare	Nobel Replace WP, Nobel Replace Select WP, Nobel Speedy Replace WP, Implant Direct 5.0		
[AN]	RePlant, BlueSky Bio 5.0 Trilobe		
Nobel Biocare	Nobel Conical Connection RP, Blue Sky Bio Max		
[AP]			
Nobel Biocare	Nobel Conical Connection NP		
[AY]			
Astra Dental [AJ]	Astra 4.5 / 5.0, Blue Sky Bio Conus 12 4.5 / 5.0		
Astra Dental [AK]	Astra 3.5 / 4.0, Blue Sky Bio Conus 12 3.5 / 4.0		
Zimmer Dental	Zimmer TSV 5.7mm, Implant Direct Legacy 5.7, BioHorizon 5.7		
[BF]			

# Steringeld Ordes a pilotessed under FOIA Request # 2016-1128; Released by CDRH on 09406421316014 Abbreviated 510(k) Premarket Notification

Nobel Biocare	3.3 Fixture, 3.75 Fixture, 4.0 Fixture, 5.0 Fixture (Old Version), 3.75 MkII Self-tapping Fixture			
Brånemark System	4.0 MkII Self-tapping Fixture			
[A]	A TERRITOR OF THE CONTROL OF THE CON			
Sterngold-	3.3 Hex Cylinder, 4.0 Hex Cylinder, 3.75 Standard Hex Screw, 3.75 Self-tapping Hex Screw,			
ImplaMed [A]	3.75 Self-tapping "SST" Hex Screw, 4.0 Standard Hex Screw, 4.0 Self-tapping Hex Screw, 4.0			
	Self-tapping "SST" Hex Screw, 4.0 Self-tapping "SST" Hex Screw, 5.0 RP "SST" Hex Screw,			
	3.75 RP Acid Etched, 4.0 RP Acid Etched, 5.0 RP Acid Etched			
Sterngold-	4.1 Stern IC (4.8 head), 3.3 Stern IC (4.8 head)			
ImplaMed [S]	3.8 HL Cylinder, 3.8 HL Threaded, 4.5 HL Threaded			
Nobel Biocare	3.8 HL Cylinder, 3.8 HL Tilleaded, 4.3 HL Tilleaded			
(Steri-Oss®) [A]	3.5 NobelReplace™, Replace® Select (NP)			
Nobel Biocare	3.5 NobelReplace, Replace Select (111)			
(Steri-Oss®) [Z] Nobel Biocare	4.0 NobelReplace Straight, (RP), 4.3Replace®Select&NobelReplace™ (RP)			
(Steri-Oss®) [T]	4.0 Nobeliceplace Straight, (Kr.), 4.5 Replace 3 colored to 5 metro.			
Keystone	3.75 Restore® Self-tapping Screw, 4.0 Restore® Self-tapping Screw, 3.75 Restore® External			
(Lifecore) [A]	Hex Screw, 4.0 Restore® External Hex Screw, 4.0 Restore® External Hex Cylinder, 4.2			
(Encoore) [, r]	Sustain® External Hex Cylinder, 3.75 Sustain® External Hex Screw, 4.0 Sustain® External			
	Hex Screw, 4.2 Sustain® External Hex MC Cylinder,			
Keystone	Stage-1 <sup>TM</sup> (3.3 and 4.0 fixtures)			
(Lifecore) [S]				
3i Implant	3.25 External Hex Miniplant®, 3.25 ICE TM Miniplant®, 3.25 OSSEOTITE® Miniplant®, 3.3			
Inovations [A]	Cylinder Miniplant®, 3.3 External Hex Cylinder, 3.75 ICE <sup>TM</sup> Self-tapping, 3.75			
	OSSEOTITE®, 3.75 Self-tapping Threaded, 3.75 Standard Threaded, 4.0 External Hex			
	Cylinder, 4.0 ICE TM Self-tapping,			
3i Implant	TG OSSEOTITE® (4.8 Platform)			
Inovations [S]	THE LANGE AND CHARLES AND OCCUPATION			
3i Implant	4.0 OSSEOTITE®, 4.0 Standard Threaded, 4.25 External Hex Cylinder, 4.0 OSSEOTITE®			
Inovations [X]	Certain TM, 4.0 OSSEOTITE® NTCertain TM, 4.0 OSSEOTITE® CERTAIN PREVAIL, 5.0			
YA CORD CI	Osseotite® Certain, 5.0 Osseotite® NT Certain, 5.0 Osseotite® Certain Prevai 3.3 Universal Flare Cylinder, 3.75 Universal Self-tapping, 3.75 Universal Self-tapping Coated,			
IMTEC	4.0 Spike Cylinder, 4.0 Universal Cylinder			
Corporation® [A]	3.3 Hex Cylinder, 3.75 Self-tapping Threaded, 4.0 Hex Cylinder, 4.0 Self-tapping Threaded,			
Interpore IMZ [A]	4.25 Hex Cylinder			
Ocatom [A]	4.1 US II, III, II Plus			
Osstem [A] Osstem [S]	ST III (1 2 head)			
Zimmer Dental[A]	3.5 Bio-Vent® X <sup>TM</sup> , 3.75 Swede-Vent <sup>TM</sup> Conical Neck CST, 3.75 Swede-Vent <sup>TM</sup> Standard,			
Zimmer Demai[A]	4.0 Swede-Vent TM Standard, 4.0 Bio-Vent® X TM,			
Zimmer Dental [B]	3.25 Micro-Vent® (3.5 head), 3.3 Screw-Vent® (3.5 head), 3.5 Bio-Vent® (3.5 head), 3.7			
Zimmer Dentar [D]	Screw-Vent® (3.5 head), 3.75 Screw-Vent® (3.5 head), 4.3 Core-Vent® (3.5 head)			
Zimmer Dental [C]	4.25 Micro-Vent® (4.5 head), 4.5 Bio-Vent® (4.5 head), 4.7 Screw-Vent® (4.5 head), 5.3			
Zimmor Bontar [0]	Core-Vent® (4.5 head)			
Zimmer Dental [S]	3.7 Tapered Swiss Plus TM (4.8 platform), 4.8 Tapered Swiss Plus A.1 Straight Swiss Plus A.1 Straight Swiss Plus TM			
[2]	4.8 Straight Swiss Plus TM			
Zimmer	3.75 ThreadLocTM			
(Calcitek®,				
Centerpulse) [A]	TAA			
Straumann [S]	ITI TE <sup>TM</sup> 3.3 (4.8 head), ITI 3.3 Std & Std Plus (4.8 head), ITI TE <sup>TM</sup> 4.1 (4.8 head), ITI 4.1			
	Std. & Std. Plus (4.8 head), ITI, 4.8 Std. & Std. Plus (4.8 head)			



	A CONTRACTOR AND A CONT		
Biolok	4.5 Silhouette Screw, 4.0 Micro-Lok Screw, 4.0 Micro-Lok Cylinder, 3.75 Micro-Lok Screw,		
International [A]	3.3 Micro-Lok Cylinder		
Bud [A]	3.25 Bud Screwvent, 3.75 Bud Screwvent		
INNOVA [A]	4.1 ENDOPORE® External Connection, 4.0 ENTEGRATM External Connection		
OIC [A]	3.0 Osteo Standard ST, 3.25 Osteo Standard ST, 3.75 Osteo Standard ST		
MIS IMPLANTS			
[B]	3.3mm Internal Hex, 3.75mm Internal Hex, 4.20mm Internal Hex		
MIS IMPLANTS	5.0mm Internal Hex		
[C]			
BioHorizons® [B]	3.5 Internal, 3.5 Single Stage		
BioHorizons® [C]	4.0 Internal, 4.5 Internal, 4.5 Single Stage		
Implant Direct [B]	Legacy 3.5mm, 3.7mm ScrewPlant,		
Implant Direct C]	Legacy 4.5mm, 4.7mm ScrewPlant		
Implant Direct [T]	RePlant™ 4.3mm		
Implant Direct [Z]	RePlant™ 3.5mm		
Minimatic/Stryker	3.3 External Hex Cylinder, 3.75 External Hex Screw, 4.0 External Hex Cylinder, 4.0 External		
[A]	Hex Screw, 4.75 External Hex Screw, 5.0 External Hex Cylinder		

**Operation Mechanism** 





**Material Composition:** 

The ORA Implant Abutments are manufactured by the same strict standards as previous Sterngold devices and from the same materials used to manufacture previously devices cleared by K130183 and K132814.

- ORA Implant abutment Wrought Titanium 6 Al-4V ELI Alloy, ASTM F136.
- ORA Retaining Ring (b)(4) Stainless Steel, ASTM A582.

• Red Processing O-Ring - (b)(4)

White Final O-Ring – (b)(4)

(21 CFR 177.2600 FDA approved ingredients intended for repeated use).

The proposed devices do not contain or utilize software.

### Components/Accessories:

ORA Retaining Ring – 914065 Red Processing O-Ring – 909011 White Final O-Ring - 909012

MR Safety: The ORA Implant Abutments are manufactured from a non-ferromagnetic material: 6AL-4V ELI titanium.

The ORA Implant Abutments have not been evaluated for safety and compatibility in the MR environment. The ORA Implant Abutments have not been tested for heating or migration in the MR environment. These statements are included in the Instructions for Use.

The proposed abutments are only provided straight and are not intended to be modified to an angle.

The proposed ORA Implant Abutments are listed on Table B. This table is a complete list of the devices/models that need marketing clearance.

Refer to Table C for a 3D photograph of an ORA Abutment.



### SUBSTANTIAL EQUIVALENCE

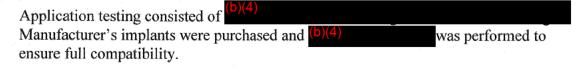
The proposed ORA Implant Abutments are substantially equivalent to the currently marketed implant predicate devices. The intended use, basic design, fundamental operating principles and manufacturing procedures are the same as the predicate devices. To ensure compatibility the following process was carried out: The implant abutments were designed, developed, and manufactured according to manufacturer's specifications and controlled procedures. A validation protocol was done in accordance with Design Control requirements per FDA CFR820.30.

K900099	The O-Ring System – ORS
K130183	SFI Bar® Implant Abutments for 7 Platforms
K132814	SFI Bar® Implant Abutments for 9 Platforms

Compatibility was determined by comparing the design features including diameters, lengths, cuff sizes, materials, implant/abutment interface connection, and intended use of the proposed device to predicate devices.

The ORA Abutments are an exact replica of the ORS abutments previously cleared by K900099. There are no differences between the proposed device and the predicate device, which we claim substantial equivalence (K900099). Based on this the proposed device renders no NSE.

Substantial equivalence was established based on intended use, design, materials, chemical composition, manufacturing process, performance, safety, effectiveness, labeling, and biocompatibility.



Continuous compatibility with manufacturer's implants indicated on this application and respective abutments will be verified every nonths by (b)(4) to ensure compatibility.

The summary of technological characteristics, tolerance analysis, application and functional testing indicate that the device is safe and effective for its intended use and performs as well or better than the predicate devices.

Table A summarizes the substantial equivalence comparison to the predicate devices.



Table A

Attribute	Candidate	Hb. H° 4 Hb.	
According	Candidate	Predicate Device	Predicate Device
	The ORA Implant Abutment Sterngold Dental, LLC	The O-Ring System – ORS Attachments International, Inc. K900099	SFI Implant Abutments Sterngold Dental, LLC K130183, K132814
Design/Construction	Machined, screw-retained	Machined, screw-retained	Machined, screw-retained
Anatomical Site	Oral Cavity	Oral Cavity	Oral Cavity
Device Material	Wrought Titanium-6AL-4 Vanadium ELI Alloy	Wrought Titanium-6AL-4 Vanadium ELI Alloy	Wrought Titanium-6AL-4 Vanadium ELI Alloy
Indications for Use	Indicated for use with dental implants to support and/or retain removable dental prostheses in the treatment of partially or totally edentulous patients to restore chewing function. The abutment screws directly into endosseous implants.	The ORS Implant Abutments are intended for use with dental implants as a support or attachment for prosthetic restoration. The abutment screws directly into the implant.	The SFI-Bar® Implant Abutments are indicated for use with dental implant bodies/fixtures to support and /or retain removable dental prostheses for partially or totally edentulous patients to restore chewing function.
Operating Principle/ Basic Design	Abutment Implant connection: Screw fixation	Abutment Implant connection: Screw fixation	Abutment Implant connection: Screw fixation
	Connecting principle to overdenture: Retentive system	Connecting principle to overdenture: Retentive system	Connecting principle to overdenture: Retentive system
	Cleaning procedures for patient: Common procedure for oral hygiene	Cleaning procedures for patient: Common procedure for oral hygiene	Cleaning procedures for patient: Common procedure for oral hygiene
	Patient handling: Common cleaning and insertion of denture	Patient handling: Common cleaning and insertion of denture	Patient handling: Common cleaning and insertion of denture
Packaging, materials and processes	Produced in a controlled CNC machine process, previously validated Packaging: Pouch Non-sterile	Produced in a controlled CNC machine process, previously validated Packaging: Pouch Non-sterile	Produced in a controlled CNC machine process, previously validated Packaging: Pouch Non-sterile
	0.4, 1.0, 1.25, 2.0, 3.0, 4.0, 5.0mm	1.0, 2.0, 3.0, 4.0, 5.0, 6.0, 7.0mm	1.0, 1.5,1.75, 2.0, 2.2, 2.5, 3.0, 3.5, 4.0, 4.5, 5.0, 5.5mm
Connection	RP, Conical, NP, WP, 3.5 Head, 4.0 Head, 4.1 Head, 4.5 Head, 4.8 Head	RP, Conical, NP, WP, 3.5 Head, 4.0 Head, 4.1 Head, 4.5 Head, 4.8 Head	RP, Conical, NP, WP, 3.5 Head, 4.0 Head, 4.1 Head, 4.5 Head, 4.8 Head



Biolok International	4.5 Silhouette Screw, 4.0 Micro-Lok Screw, 4.0 Micro-Lok Cylinder, 3.75 Micro-Lok Screw, 3.3		
	Micro-Lok Cylinder		
Bud	3.25 Bud Screwvent, 3.75 Bud Screwvent		
INNOVA	4.1 ENDOPORE® External Connection, 4.0 ENTEGRATM External Connection		
OIC	3.0 Osteo Standard ST, 3.25 Osteo Standard ST, 3.75 Osteo Standard ST		
MIS IMPLANTS	3.3mm Internal Hex, 3.75mm Internal Hex, 4.20mm Internal Hex, 5.0mm Internal Hex		
BioHorizons®	3.5 Internal, 4.0 Internal, 4.5 Internal, 3.5 Single Stage, 4.5 Single Stage		
Implant Direct	Legacy 3.5mm, Legacy 4.5mm, RePlant™ 4.3mm, RePlant™ 3.5mm, 3.7mm ScrewPlant, 4.7mm ScrewPlant		
Minimatic/Stryker	3.3 External Hex Cylinder, 3.75 External Hex Screw, 4.0 External Hex Cylinder, 4.0 External Hex		
	Screw, 4.75 External Hex Screw, 5.0 External Hex Cylinder		
Straumann	Straumann Bone Level RC, Blue Sky Bio Square Taper RC		
Straumann	Straumann Bone Level NC, Blue Sky Bio Square Taper NC		
Ankylos	Ankylos		
Nobel Biocare	Nobel Replace WP, Nobel Replace Select WP, NobelSpeedy Replace WP, Implant Direct 5.0		
	RePlant, BlueSky Bio 5.0 Trilobe		
Nobel Biocare	Nobel Conical Connection RP		
Nobel Biocare	Nobel Conical Connection NP, Blue Sky Bio Max		
Astra Dental	Astra 4.5 / 5.0, Blue Sky Bio Conus 12 4.5 / 5.0		
Astra Dental	Astra 3.5 / 4.0, Blue Sky Bio Conus 12 3.5 / 4.0		
Zimmer Dental	Zimmer TSV 5.7mm, Implant Direct Legacy 5.7, BioHorizon 5.7		

The proposed devices are for single use only and are supplied non-sterile.

MR Safety: The ORA Implant Abutments are manufactured from a non-ferromagnetic material: 6AL-4V ELI titanium.

The ORA Implant Abutments have not been evaluated for safety and compatibility in the MR environment.

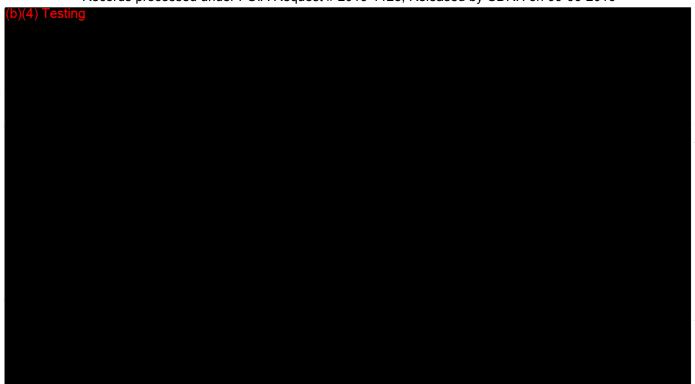
The ORA Implant Abutments have not been tested for heating or migration in the MR environment. These statements are included in the Instructions for Use.

The proposed devices do not contain or utilize software.

The labeling on the proposed device was developed in compliance with ANSI/AAMI/ISO 15223-1:2012.

• ISO 15223-1:2012, Medical Devices - Symbols to be used with medical device labels, labeling, and information to be supplied - Part 1: General requirements







(b)(4)



Tolerance Analysis

(b)(4)

Tolerance Analysis

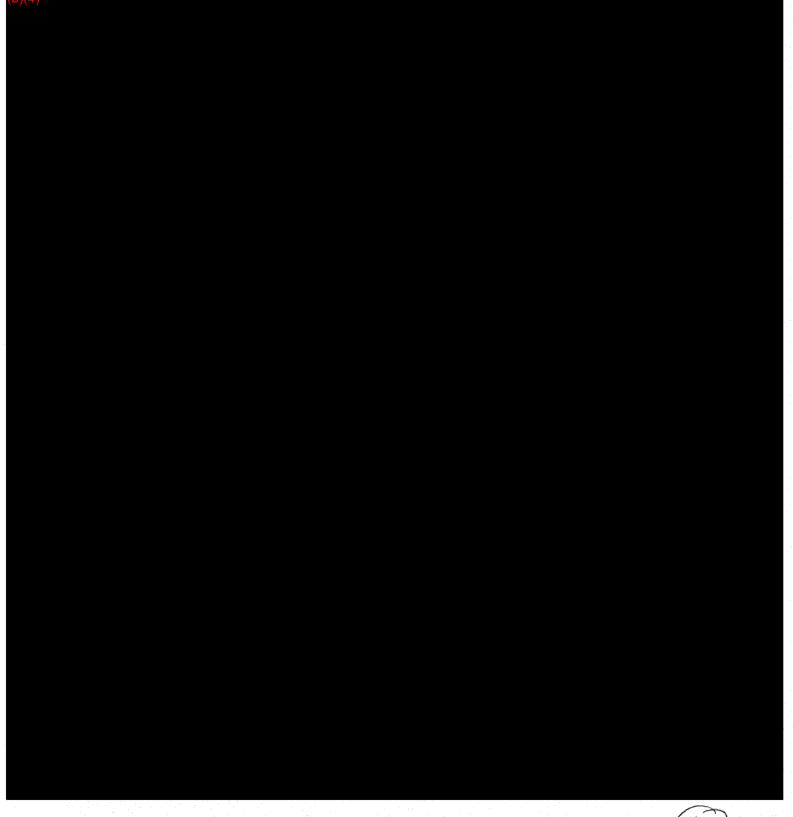
(II)





(b)(4)

(14)



Request # 2016-1128; Released by CDRH on 09-06-2016 **Tolerance Analysis** 



Recor (b)(4) Testing
(b)(4)

(20)

(b)(4)





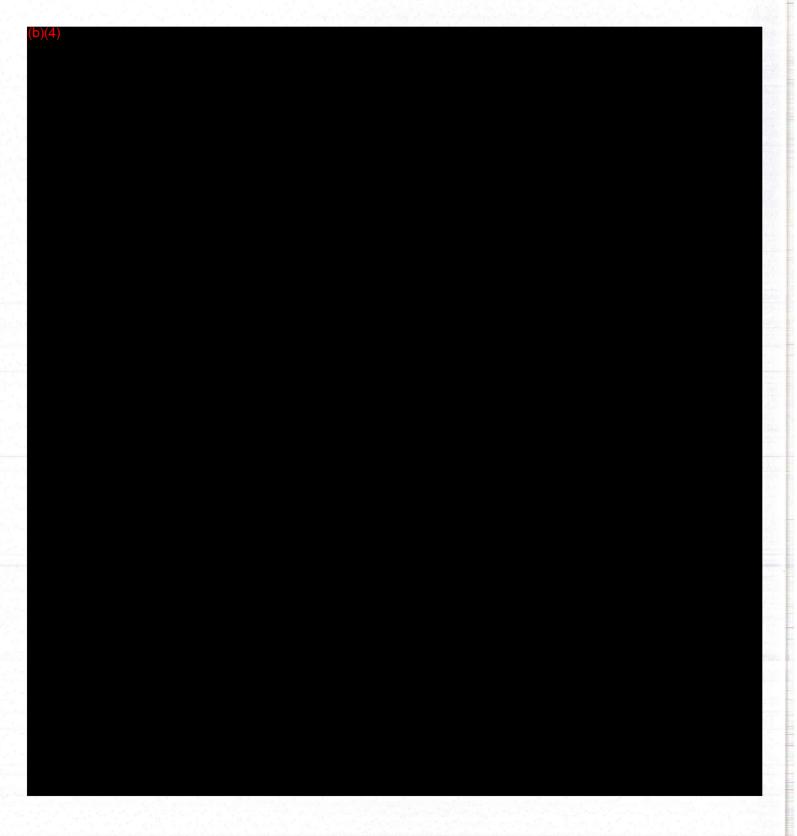
Request # 2016-1128; Released by CDRH on 09-06-2016 **Tolerance Analysis** 







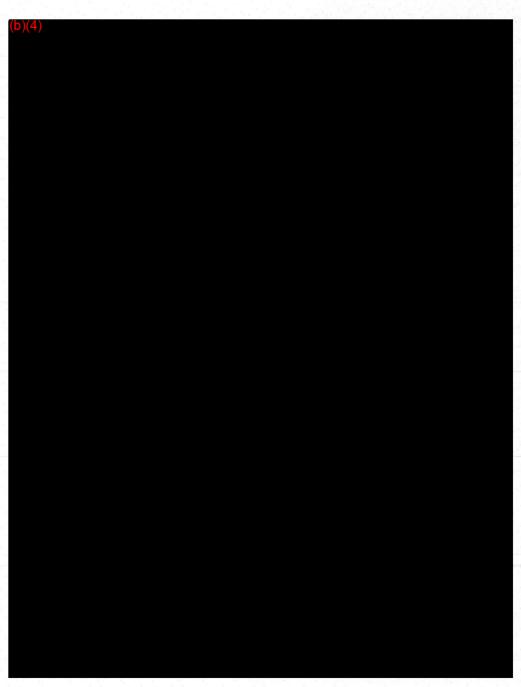




(b)(4)

Sterilization Validation





(b)(4)

Sterilization Validation



## **ATTACHMENT H**

### **INSTRUCTIONS FOR USE**

**SECTION 12** 





23 Frank Mossberg Drive Attleboro, MA 02703 800.243.9942 • 508.226.5660 www.sterngold.com

### **ORA Implant Abutments**

Instructions for Use Sterngold Dental

#### **ENGLISH**

Before using the ORA Implant Abutments, the clinician in charge should carefully study the indications, contraindications, recommendations, warnings and instructions, as well as all other product-specific information (technical product description, description of the surgical and restorative technique, catalogue sheet, etc.) and fully comply with them. Detailed instructions over and above those contained in these instructions for use can be found in the technical user's guide. It is also recommended to attend the appropriate user-training courses. The aforementioned documents and details of the training courses may be obtained from the appropriate representatives in the various countries. The manufacturer, the importer and the suppliers of the ORA Implant Abutments are not liable for complications, other negative effects or damages that might occur for reasons such as incorrect indications, unsuitable choice of material or handling thereof, unsuitable use or handling of the instruments, asepsis and so on. The clinician is responsible for any such complications or other consequences. It is also the clinician's responsibility to properly instruct and inform the patient on the functions, handling and necessary care of the product and on all known product risks.

#### INDICATIONS/INTENDED USE

The ORA Implant Abutment System is indicated for use with dental implants to support and/or retain removable dental prostheses in the treatment of partially or totally edentulous patients to restore chewing function. The abutment screws directly into endosseous implants or they screw into SFI Abutments which are screwed into endosseous implants.

The ORA Implant Abutments are compatible with the following implant systems:

Implant Brand	Model		
Nobel Biocare Brånemark System	MkII Self-tapping Fixture		
Sterngold-ImplaMed	3.3 Hex Cylinder, 4.0 Hex Cylinder, 3.75 Standard Hex Screw, 3.75 Self-tapping Hex Screw, 3.75 Self-tapping "SST" Hex Screw, 4.0 Standard Hex Screw, 4.0 Self-tapping "SST" Hex Screw, 5.0 RP "SST" Hex Screw, 3.75 RP Acid Etched, 4.0 RP Acid Etched, 5.0 RP Acid Etched, 4.1 Stern IC (4.8 head), 3.3 Stern IC (4.8 head)		
Nobel Biocare (Steri-Oss®)	3.8 HL Cylinder, 3.8 HL Threaded, 4.5 HL Threaded, 3.5 NobelReplace™, Replace® Select (NF 4.0 NobelReplace Straight, (RP), 4.3Replace®Select&NobelReplace™ (RP)		
Keystone (Lifecore)	3.75 Restore® Self-tapping Screw, 4.0 Restore® Self-tapping Screw, 3.75 Restore® External Hex Screw, 4.0 Restore® External Hex Screw, 4.0 Restore® External Hex Cylinder, 4.2 Sustain® External Hex Cylinder, 3.75 Sustain® External Hex Screw, 4.0 Sustain® External Hex Screw, 4.2 Sustain® External Hex MC Cylinder, Stage-1TM (3.3 and 4.0 fixtures)		
3i Implant Inovations	3.25 External Hex Miniplant®, 3.25 ICE <sup>™</sup> Miniplant®, 3.25 OSSEOTITE® Miniplant®, 3.3 Cylinder Miniplant®, 3.3 External Hex Cylinder, 3.75 ICE <sup>™</sup> Self-tapping, 3.75 OSSEOTITE®, 3.75 Self-tapping Threaded, 3.75 Standard Threaded, 4.0 External Hex Cylinder, 4.0 ICE <sup>™</sup> Self-tapping, 4.0 OSSEOTITE®, 4.0 Standard Threaded, 4.25 External Hex Cylinder, TG OSSEOTITE® (4.8 Platform), 4.0 OSSEOTITE® Certain <sup>™</sup> , 4.0 OSSEOTITE® NTCertain <sup>™</sup> , 4.0 OSSEOTITE®CERTAIN PREVAIL, 5.0 Osseotite® Certain, 5.0 Osseotite® NT Certain, 5.0 Osseotite®Certain Prevail		
IMTEC Corporation®	3.3 Universal Flare Cylinder, 3.75 Universal Self-tapping, 3.75 Universal Self-tapping Coated, 4.0 Spike Cylinder, 4.0 Universal Cylinder		
Interpore IMZ <sup>TM</sup>	3.3 Hex Cylinder, 3.75 Self-tapping Threaded, 4.0 Hex Cylinder, 4.0 Self-tapping Threaded, 4.25 Hex Cylinder		
Osstem	4.1 US II, III, II Plus, III Plus, SS II, III (4.8 head)		

610371 Rev A

Zimmer Dental	3.5 Bio-Vent® X <sup>™</sup> , 3.75 Swede-Vent <sup>™</sup> Conical Neck CST, 3.75 Swede-Vent <sup>™</sup> Standard, 4.0	
	Swede-Vent <sup>™</sup> Standard, 4.0 Bio-Vent® X <sup>™</sup> , 3.25 Micro-Vent® (3.5 head), 3.3 Screw-Vent® (3.5	
Records pro	head), 3.5 Bio-Vent® (3.5 head), 3.7 Screw-Vent® (3.5 head), 3.75 Screw-Vent® (3.5 head), 4.3 cessed-vent® (3.5 head), 4.3 kesses vento (4.5 head), 4.3 head), 4.3 head), 4.3 head), 4.3 head), 4.3 head), 4.3	
	head), 5.3 Core-Vent® (4.5 head), 3.7 Tapered Swiss Plus <sup>TM</sup> (4.8 platform), 4.8 Tapered Swiss Plus <sup>TM</sup> 4.1 Straight Swiss Plus <sup>TM</sup> , 4.8 Straight Swiss Plus <sup>TM</sup>	
7: (Calaitak® Cantagoulas)	3.75 ThreadLoc <sup>™</sup>	
Zimmer (Calcitek®, Centerpulse)	3.75 InteadLoc	
Straumann	ITI TE <sup>™</sup> 3.3 (4.8 head), ITI 3.3 Std & Std Plus (4.8 head), ITI TE <sup>™</sup> 4.1 (4.8 head), ITI 4.1 Std. & Std. Plus (4.8 head), ITI, 4.8 Std. & Std. Plus (4.8 head)	
Biolok International	4.5 Silhouette Screw, 4.0 Micro-Lok Screw, 4.0 Micro-Lok Cylinder, 3.75 Micro-Lok Screw, 3.3 Micro-Lok Cylinder	
Bud	3.25 Bud Screwvent, 3.75 Bud Screwvent	
INNOVA	4.1 ENDOPORE® External Connection, 4.0 ENTEGRATM External Connection	
OIC	3.0 Osteo Standard ST, 3.25 Osteo Standard ST, 3.75 Osteo Standard ST	
MIS IMPLANTS	3.3mm Internal Hex, 3.75mm Internal Hex, 4.20mm Internal Hex, 5.0mm Internal Hex	
BioHorizons®	3.5 Internal, 4.0 Internal, 4.5 Internal, 3.5 Single Stage, 4.5 Single Stage	
Implant Direct	Legacy 3.5mm, Legacy 4.5mm, RePlant™ 4.3mm, RePlant™ 3.5mm, 3.7mm ScrewPlant, 4.7mn ScrewPlant	
Minimatic/Stryker	3.3 External Hex Cylinder, 3.75 External Hex Screw, 4.0 External Hex Cylinder, 4.0 External Hex Screw, 4.75 External Hex Screw, 5.0 External Hex Cylinder	
Straumann	Straumann Bone Level RC, Blue Sky Bio Square Taper RC	
Straumann	Straumann Bone Level NC, Blue Sky Bio Square Taper NC	
Ankylos	Ankylos	
Nobel Biocare	Nobel Replace WP, Nobel Replace Select WP, NobelSpeedy Replace WP, Implant Direct 5.0 RePlant, BlueSky Bio 5.0 Trilobe	
Nobel Biocare	Nobel Conical Connection RP	
Nobel Biocare	Nobel Conical Connection NP, Blue Sky Bio Max	
Astra Dental	Astra 4.5 / 5.0. Blue Sky Bio Conus 12 4.5 / 5.0	
Astra Dental	Astra 3.5 / 4.0, Blue Sky Bio Conus 12 3.5 / 4.0	
Zimmer Dental	Zimmer TSV 5.7mm, Implant Direct Legacy 5.7, BioHorizon 5.7	

#### CONTRAINDICATIONS

The ORA Implant Abutments can only be screwed into compatible Implant. They should not be used by anyone with allergies or hypersensitivity to titanium alloy, Ti 6AI 4V.

#### WARNINGS

The ORA Implant Abutments should not be used unless the dental implants are stable and there are no signs of infection or severe bone loss. Poor bone quality, poor patient oral hygiene, heavy tobacco use, uncontrolled systemic diseases (diabetes, etc.), reduced immunity, alcoholism, drug addiction, and psychological instability may contribute to lack of integration and/or subsequent implant failure. Severe bruxism, clenching, and overloading may cause bone loss, screw loosening, component fracture, and/or implant failure. Exposure to radiation and chemotherapy may impact health of the implant. Dental implant patients should be instructed to consult with their physician prior to undergoing such treatment options.

Restorative techniques required to place and restore dental implants are highly specialized and complex procedures. Practitioners should attend courses of study to familiarize themselves with implantology techniques. Improper technique can cause bone loss and implant failure.

Other relative contraindications include steroid and anticoagulant treatment which may affect the surgical site, surrounding tissue, or patient's healing function. Exposure to long-term use of bisphosphonate drugs especially with chemotherapy may impact implant survival. Careful patient selection including consultation with the attending physician is strongly recommended prior to implant treatment. Excessive mobility, bone loss, or infection may indicate the implant is failing. Any implant which appears to be failing should be treated or removed as soon as possible. If removal is necessary, curette any soft tissue from the implant site and allow site to heal as though it were an atraumatic extraction. Due to the metal conductivity, electrosurgery around the implants and intraoral abutment preparations without irrigation could result in tissue damage and implant failure. Patients should consult with their physician and imaging technician prior to undergoing an MRI procedure.

The proposed abutments are only provided straight and are not intended to be modified to an angle.

#### **PRECAUTIONS**

Proper case planning is essential to the long-term success of both the prostheses and the implants. Overload is one of the key contributors to implant failure. Ensure the implant angle corrections are appropriate for the occlusal load.

#### **Breakage**

Implant fractures can occur when applied loads exceed the normal functional design tolerances of the implant components. Potential overloading conditions may result from deficiencies in implant numbers, lengths and/or diameters to adequately support a restoration, excessive cantilever length, incomplete abutment seating, abutment angles greater than 30 degrees, occlusal interferences causing excessive lateral forces, patient parafunction (e.g. bruxing, clenching), improper denture manufacture procedures, inadequate denture fit, and physical trauma.

Changes in Performance

It is the responsibility of the clinician to instruct the patient on all appropriate contraindications, side effects, and precautions as well as the need to seek the services of a trained dental professional if there are any changes in the performance of the implant (e.g., looseness of the prosthesis, infection or exudate around the implant, pain, or any other unusual symptoms that the patient has not been told to expect).

Hygiene & Maintenance

Long-term implant health is directly related to the maintenance of oral hygiene. Potential implant candidates should establish an adequate oral hygiene

2 of 4 Pages

610371 Rev A

regimen prior to implant therapy. Following implant placement, the clinician should instruct the patient on proper tools and techniques to ensure long-term maintenance of the implant(s). The patient should also be instructed to maintain routinely scheduled prophylaxis and evaluation appointments.

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Control of biomechanical stresses is the key factor to long-term success of the prosthesis. Even after implant integration, imbalances in occlusal forces can lead to implant failure. Implant patients should be monitored for signs of peri-implant bone loss and excessive attachment wear as signs of occlusal overloading.

**ADVERSE EFFECTS** 

The following complications may occur relative to implant placement: pain, discomfort, dehiscence, delayed healing, paresthesia, hyperesthesia, edema, hemorrhage, hematoma, infection, inflammation, local and generalized allergic reaction, lack of integration, loss of bone, and loss of implant. Other adverse effects may also occur as a result of iatrogenic factors and host responses.

Single Use

Reuse of a single use device that has come in contact with blood, bone, tissue or other body fluids may lead to patient or user injury. Possible risks associated with reuse of a single use device include, but are not limited to, mechanical failure and transmission of infectious agents.

**Product Packaging** 

ORA Implant Abutments are packaged in a sealed chevron pouch. These pouches are not autoclavable. Parts need to be removed from pouch prior to autoclaving and placed in an autoclavable pouch or tray.

#### **CLEANING/STERILIZATION INFORMATION**

Sterngold Dental prosthetic and ancillary components are sold non-sterile. Sterilize or disinfect according to the procedures below prior to use in patients.

The autoclave is to be used according to manufacturer instructions. The health care facility should monitor the sterilizer for the facility according to an FDA recognized sterility assurance standard such as ANSI/AAMI ST79.

Disinfection and sterilization procedures should conform to OSHA or local guidelines for blood borne pathogens.

Non Sterile Abutments shall be sterilized using steam sterilization and a gravity placement autoclave. The following sterilization parameters (method, time, and temperature) are required to achieve a 10-<sup>6</sup> sterility assurance level (SAL). Local or national specifications should be followed where steam sterilization requirements are stricter or more conservative than those listed below.

Caution: It is the responsibility of the user to establish whether or not their sterilizer has been cleared by the FDA to meet these recommended parameters, and to use accessories (Bls, Cls, and wraps/pouches/containers) cleared by FDA and labeled for use.

Cleaning

Use the following guidelines for cleaning products:

Rinse with cool-to-lukewarm water for two-and-one-half minutes. For all parts place in an ultrasonic cleaner with an enzymatic detergent diluted with tap water per the manufacture's guidelines. Sonicate for 10 minutes. Rinse with tap water for three minutes.

Sterilization

Individual parts shall be placed in appropriate autoclave using steam sterilization. The following sterilization parameters (method, time, and temperature) are required to achieve a 10-<sup>6</sup> sterility assurance level (SAL).

To ensure autoclave is performing effectively, periodic use of biologic indicators should be considered.

Cycle Type: Steam Sterilization Temperature: 121°C / 250°F Exposure Time: 30 minutes Dry Time: 15 - 30 minutes

**Operation Mechanism** 

Choose the abutment with the proper cuff height that fits the existing implant or choose the ORA Abutment that will screw into an SFI Abutment. Screw an abutment into each implant or SFI Abutment. The abutments are tightened to 20 Ncm, using a hex tool which engages the hex at the base of the

Once the O-Ring Abutments are in place, an impression is taken using a light impression material. Impression is sent to the laboratory so that the denture can be created.

The O-Ring Abutments can remain in place while the denture is being created.

The laboratory will incorporate the O-Ring Retainers into the denture. After the material has cured, the denture is removed. The red o-ring is pulled out of the metal housing and the white o-ring is inserted into its place.

The denture is then snapped onto the ball abutment in the patient's mouth.

O-Ring Placement Procedure:

The retaining ring (metal housing) comes with the red o-ring (which is a firm rubber) inside. The retaining ring (metal housing) with the red o-ring is pushed over the wide part of the ball until seated. The stiffness of the red o-ring holds the housing in position. Any exposed areas of the abutment are blocked out so that only the metal housing is exposed. The retaining ring (metal housing) is then processed into the denture. After the material has cured, the denture is removed. The red o-ring is pulled out of the metal housing and the white o-ring is inserted into its place. The white o-ring is more flexible making insertion and removal easier.

MR Safety: The ORA Implant Abutments are manufactured from a non-ferromagnetic material: 6AL-4V ELI titanium.

The ORA Implant Abutments have not been evaluated for safety and compatibility in the MR environment.

The ORA Implant Abutments have not been tested for heating or migration in the MR environment.

The proposed devices do not contain or utilize software.

3 of 4 Pages

610371 Rev A

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8148

Manufactured and Directords processed under FOIA Request # 2016-1128; Released by CDRH on 09-06-2016 Sterngold Dental, LLC 23 Frank Mossberg Drive Attleboro, MA 02703-0967 USA 1-800-243-9942 or 508-226-5660

European Representative: Federico Perex San Prudencio 25 Vitoria 01005 Spain

Ph: +34 945 230 736 Fax: +34 945 230 236

Label Symbol	Used For	Symbol	Used For
	Do not reuse	NON	Symbol for Non- Sterile
REF	Catalog number	LOT	Batch code
	Manufacturer		Caution, consult accompanying documents
Ronly	Symbol for "Use by Prescription only"	CE	Symbol for "European Conformity"
EC REP	Authorized representative in the European Community	e e i se estador e esta por est. Accedenda	Sabrimating programmy reclaimed a program process in a part of the part of the process in a part of the

## **ATTACHMENT I**

**510 (k) Summary** 

**SECTION 13** 

### 510(k) Summary

Sponsor:

Sterngold Dental, LLC

23 Frank Mossberg Drive Attleboro, MA 02703

Contact:

Maria Rao, QA/RA Director Ph: 508-226-5660 ext 1206

**Trade Name:** 

**ORA** Implant Abutments

Common Name:

Implant Abutments

Classification Name: Endosseous Dental Implant Abutment

**Classification:** 

According to Section 513 of the Federal Food, Drug, and

Cosmetic Act, the device classification is Class II

**Product Code:** 

NHA (21CFR 872.3630)

Legally Marketed Device to which Equivalence is claimed (Predicate Devices):

Predicate Device(s): K900099, K130183, K132814.

K900099

The O-Ring System – ORS

K130183

SFI Bar® Implant Abutments for 7 Platforms

K132814

SFI Bar® Implant Abutments for 9 Platforms

#### **Description of Device:**

The ORA Implant Abutment is a precision machined ball shaped abutment that connects a compatible dental implant system with a removable partial or complete overdenture. The implant abutment is screwed into the dental implant. Connection to and retention of a denture is provided by a rubber o-ring, which may or may not be held within a metal housing. There are two color o-rings, a red processing o-ring and a white final o-ring.

The retaining ring (metal housing) comes with the red o-ring (which is a firm rubber) inside. The retaining ring (metal housing) with the red o-ring is pushed over the wide part of the ball until seated. The stiffness of the red o-ring holds the housing in position. Any exposed areas of the abutment are blocked out so that only the metal housing is exposed. The retaining ring (metal housing) is then processed into the denture. After the material has cured, the denture is removed. The red o-ring is pulled out of the metal housing and the white o-ring is inserted into its place. The white o-ring is more flexible making insertion and removal easier.

The bottom portion of the abutment (cuff area to end of threads) is an exact replica of the SFI Implant Abutments previously cleared by K130183 and K132814.

## Comparison/Compatibility Substantial Equivalence:

The proposed implant abutments are substantially equivalent to the currently marketed predicate devices. The intended use, basic design, fundamental operating principles and manufacturing procedures are the same as the predicate devices.

To ensure compatibility the following process was carried out: The implant abutments were designed and developed, and manufactured according to manufacturer's specifications and controlled procedures. A validation protocol was done in accordance with Design Control requirements per FDA CFR820.30.

Table 2 summarizes the substantial equivalence comparison to the predicate devices.

#### Performance Data:

Application and functional testing have been conducted to evaluate the performance characteristics of the ORA Implant Abutments. The test methods used were the same as in predicate devices. Testing has shown that the ORA Implant Abutments included in this application are equivalent in performance characteristics to its predicate devices. The acceptance criteria were met. Refer to Test Report.

# Summary of Testing to Demonstrate Safety and Effectiveness / Conclusion:

Non-clinical test data was used to support the substantially equivalence claim. Clinical testing was not necessary. The non-clinical testing consisted of tolerance analysis of platforms to identify worst case test samples. Fatigue testing was not done as the basic design is the same as the predicate devices. The evaluation was based on FDA guidance "Class II Special Controls Guidance Document: Root-Form Endosseous Dental Implants and Endosseous Dental Implant Abutments." ((b)(4)) tests, application and functional tests have been carried out.

The summary of technological characteristics as well as application and functional testing indicate that the device is safe and effective for its intended use and performs as well or better than the predicate devices.



## Comparison/Compatibility Substantial Equivalence:

The proposed implant abutments are substantially equivalent to the currently marketed predicate devices. The intended use, basic design, fundamental operating principles and manufacturing procedures are the same as the predicate devices.

To ensure compatibility the following process was carried out: The implant abutments were designed and developed, and manufactured according to manufacturer's specifications and controlled procedures. A validation protocol was done in accordance with Design Control requirements per FDA CFR820.30.

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