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

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 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 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.O 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™	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™, 3.75 Swede-Vent™ Conical Neck CST, 3.75 Swede-Vent™ Standard, 4.0 Swede-Vent™ Standard, 4.0 Bio-Vent® X™, 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™ (4.8 platform), 4.8 Tapered Swiss Plus™ 4.1 Straight Swiss Plus™, 4.8 Straight Swiss Plus™
Zimmer (Calcitek®, Centerpulse)	3.75 ThreadLoc™
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 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

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 Connecting principle to overdenture: Retentive system Cleaning procedures for patient: Common procedure for oral hygiene Patient handling: Common cleaning and insertion of denture	Abutment Implant connection: Screw fixation Connecting principle to overdenture: Retentive system Cleaning procedures for patient: Common procedure for oral hygiene Patient handling: Common cleaning and insertion of denture	Abutment Implant connection: Screw fixation Connecting principle to overdenture: Retentive system Cleaning procedures for patient: Common procedure for oral hygiene 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 Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of 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. 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 -S

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

510(k) Number (if known): K133791

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
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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 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.O 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™	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™, 3.75 Swede-Vent™ Conical Neck CST, 3.75 Swede-Vent™ Standard, 4.0 Swede-Vent™ Standard, 4.0 Bio-Vent® X™, 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™ (4.8 platform), 4.8 Tapered Swiss Plus™ 4.1 Straight Swiss Plus™, 4.8 Straight Swiss Plus™
Zimmer (Calcitek®, Centerpulse)	3.75 ThreadLoc™
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 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

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

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'

Sterngold®

Alloys
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Restorative Systems

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

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

Sterngold®

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

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
11/26/2013	(b)(4)	

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Request for Feedback
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-Submission
☐ Premarket Report	☐ Special	☐ Notice of Completion	☐ Traditional	☐ Informational Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Submision Issue Meeting
☐ Amendment	☐ 30-day Supplement		☒ Abbreviated (Complete section I, Page 5)	☐ Day 100 Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Agreement Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Determination Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Study Risk Determination
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify)*:
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission)*:
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☒ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*		
Sterngold Dental, LLC	2921595		
Division Name *(if applicable)*	**Phone Number *(including area code)***		
	508-556-5660		
Street Address	**FAX Number *(including area code)***		
23 Frank Mossberg Drive	508-226-7528		
City	**State / Province**	**ZIP/Postal Code**	**Country**
Attleboro	MA	02703	U.S.
Contact Name			
Maria Rao			
Contact Title	**Contact E-mail Address**		
Director of Quality & Regulatory Affairs	maria.rao@sterngold.com		

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	**FAX Number *(including area code)***		
23 Frank Mossberg Drive	508-226-7528		
City	**State / Province**	**ZIP Code**	**Country**
Attleboro	MA	02703	U.S.
Contact Name			
Maria Rao			
Contact Title	**Contact E-mail Address**		
Director of Quality & Regulatory Affairs	maria.rao@sterngold.com		

PSC Publishing Services (301) 443-6740 EF

SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ 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

- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

- ☐ Process change:
  - ☐ Manufacturing ☐ Packaging
  - ☐ Sterilization
  - ☐ Other *(specify below)*

- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*

- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment

- ☐ Response to FDA correspondence:

- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

- ☐ Other Reason *(specify)*:

SECTION D2 REASON FOR APPLICATION - IDE

- ☐ 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

- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor

- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final

- ☐ 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)*:

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	DZE	2	NHA	3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

☐ 510 (k) summary attached

☐ 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K900099	1	The O-Ring System - ORS	1	Attachments International, Inc.
2	K130183	2	SFI Bar Abutments	2	Sterngold Dental, LLC
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

Endosseous Dental Implant Abutment

	Trade or Proprietary or Model Name for This Device		Model Number
1	ORA 0.4MM [S]	1	904264
2	ORA 1.0MM [S]	2	904265
3	ORA 2.0MM [S]	3	904266
4	ORA 3.0MM [S]	4	904267
5	ORA 4.0MM [S]	5	904268

FDA document numbers of all prior related submissions *(regardless of outcome)*

1	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

☐ Laboratory Testing ☐ Animal Trials ☐ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*
872.3630	21

Classification Panel

Dental

Device Class

☐ Class I ☒ Class II

☐ Class III ☐ Unclassified

Indications *(from labeling)*

The ORA Implant Abutment System is intended 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.

Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.	FDA Document Number *(if known)*

SECTION H — MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number: 10023675	☒ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name: Serngold Dental, LLC		Establishment Registration Number: 2921595	
Division Name *(if applicable)*		Phone Number *(including area code)*	
Street Address: 23 Frank Mossberg Drive		FAX Number *(including area code)*	
City: Attleboro	State / Province: MA	ZIP Code: 02703	Country: U.S.
Contact Name: Maria Rao	Contact Title: Director of QA & Regulatory Affairs	Contact E-mail Address: maria.rao@sterngold.com	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)*	
Street Address		FAX Number *(including area code)*	
City	State / Province	ZIP Code	Country
Contact Name	Contact Title	Contact E-mail Address	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)*	
Street Address		FAX Number *(including area code)*	
City	State / Province	ZIP Code	Country
Contact Name	Contact Title	Contact E-mail Address	

SECTION I UTILIZATION OF STANDARDS

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

	Standards No.	Standards Organization	Standards Title	Version	Date
1	F136-12a	ASTM	Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications	English	01/01/2012
2	15223-1: 2012	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
3	10993-1:2009	AAMI/ANSI/ISO	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process.	English	01/01/2009
4	10993-5: 2009	AAMI/ANSI/ISO	Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity	English	01/01/2009
5	F2459-12	ASTM	Standard Test Method for Extracting Residue from Metallic Medical Components and Quantifying via Gravimetric Analysis.	English	01/01/2012
6	17665-1:2006	ISO	Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices.	English	01/01/2006
7	17665-2: 2009	ISO	Sterilization of health care products - Moist heat - Part 2: Guidance on the application of ISO 17665-1.	English	01/01/2009

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

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

Addendum to Product Information - Section F of Form FDA 3514

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

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

Form Approved: OMB No. 0910-0511 Expiration Date: April 30, 2016. See Instructions for OMB Statement.

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 or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)

STERNGOLD DENTAL LLC
23 FRANK MOSSBERG DR.
--
ATTLEBORO
MA 02703
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
*****2662

2. CONTACT NAME
Maria Rao
2.1 E-MAIL ADDRESS
maria.rao@sterngold.com
2.2 TELEPHONE NUMBER (include Area code)
508-226-5660 1206
2.3 FACSIMILE (FAX) NUMBER (Include Area code)
508-226-5473

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm

Select an application type:
[X] Premarket notification(510(k)); except for third party
[ ] 513(g) Request for Information
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)
[ ] 30-Day Notice

3.1 Select a center
[X] CDRH
[ ] CBER

3.2 Select one of the types below
[X] Original Application

Supplement Types:
[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)
[X] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
NO, I am not a small business
4.1 If Yes, please enter your Small Business Decision Number: SBD138617

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?
[X] YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)
[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.
[ ] This application is the first PMA submitted by a qualified small business, including any affiliates
[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only
[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).
[ ] YES [X] NO

PAPERWORK REDUCTION ACT STATEMENT
Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850
[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION
(b)(4)
23-Sep-2013

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

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

510(k) PREMARKET NOTIFICATION SCREENING CHECKLIST

SECTION 1

Premarket Notification Screening Checklist
(Abbreviated 510(k))

	Yes/ Present	Not Present/ Not Required	Location/ Comments
Cover Letter clearly identifies the type of 510(k) submission as: Abbreviated	X		Cover Letter
Section 1: Required Elements for All Types 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 street address	X		Attachment A
• Contact person (if different from applicant)	X		Attachment A
• Telephone and FAX numbers of applicant or contact	X		Attachment A
• Signature of the applicant	X		Cover Letter
• Addresses of manufacturing and sterilization site(s) as appropriate	X		Attachment A
Table of Contents	X		Table of Contents
Truthful and Accurate Statement	X		Attachment G
Device's Trade Name, Device's Classification name and Establishment Registration Number	X		Attachment A
Device's Classification Regulation Number and Status (Class I, Class II, Class III or Unclassified)	X		Attachment A
Proposed Labeling including the information listed on page 3-4 of the Premarket Notification [510(k)] Manual	X		Attachment E
Statement of Indications for Use that is on a separate page in the premarket submission	X		Indications for Use Statement
Substantial Equivalence Comparison, including comparisons of the new device with the predicate in areas that are listed on page 3-4 of the Premarket Notification [510(k)] Manual	X		Attachment C
510(k) Summary or 510(k) Statement	X		Attachment I
Description of device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals	X		Attachment B
Identification of legally marketed predicate device*	X		Attachment C
Compliance with performance standards * [See Section 514 of the Act and 21 CFR 807.87(d)]	X		Attachment A
Class III Certification and Summary		X	
Financial Certification or Disclosure Statement for 510(k)'s notifications with a clinical study * [See 21 CFR 807.87(i)]	X		Not required – no clinical study
510(k) Kit Certification ***		X	Not a kit

* May not be applicable for Special 510(k)'s ** required for Class III devices only***
See pages 3-12 and 3-13 in the Premarket Notification [510(k)] Manual and the Convenience Kits Interim Regulatory Guidance.

	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]	X		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.		X	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.		X	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.	X		Attachment C
* List of all guidance documents, special controls, recognized standards and/or non-recognized standards, which were noted by the sponsor.	X		Attachment D

INDICATIONS FOR USE STATEMENT

SECTION 2

510(k) Number (if known): _____

Device Name: **ORA Implant Abutment System**

Indications for Use:

The ORA Implant Abutment System is intended 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.

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

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)

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 *The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications."*

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

Sterilization: N/A

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:

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 [AN]	Nobel Replace WP, Nobel Replace Select WP, NobelSpeedy Replace WP, Implant Direct 5.0 RePlant, BlueSky Bio 5.0 Trilobe
Nobel Biocare [AP]	Nobel Conical Connection RP, Blue Sky Bio Max
Nobel Biocare [AY]	Nobel Conical Connection NP
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 [BF]	Zimmer TSV 5.7mm, Implant Direct Legacy 5.7, BioHorizon 5.7
Nobel Biocare Brånemark System [A]	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 [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 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™ (3.3 and 4.0 fixtures)
3i Implant Inovations [A]	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,
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™, 4.0 OSSEOTITE® NTCertain™, 4.O 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™, 3.75 Swede-Vent™ Conical Neck CST, 3.75 Swede-Vent™ Standard, 4.0 Swede-Vent™ Standard, 4.0 Bio-Vent® X™,
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™ (4.8 platform), 4.8 Tapered Swiss Plus™ ,4.1 Straight Swiss Plus™, 4.8 Straight Swiss Plus™
Zimmer (Calcitek®, Centerpulse) [A]	3.75 ThreadLocTM
Straumann [S]	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 [A]	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 [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 [C]	5.0mm Internal Hex

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 [A]	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

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.

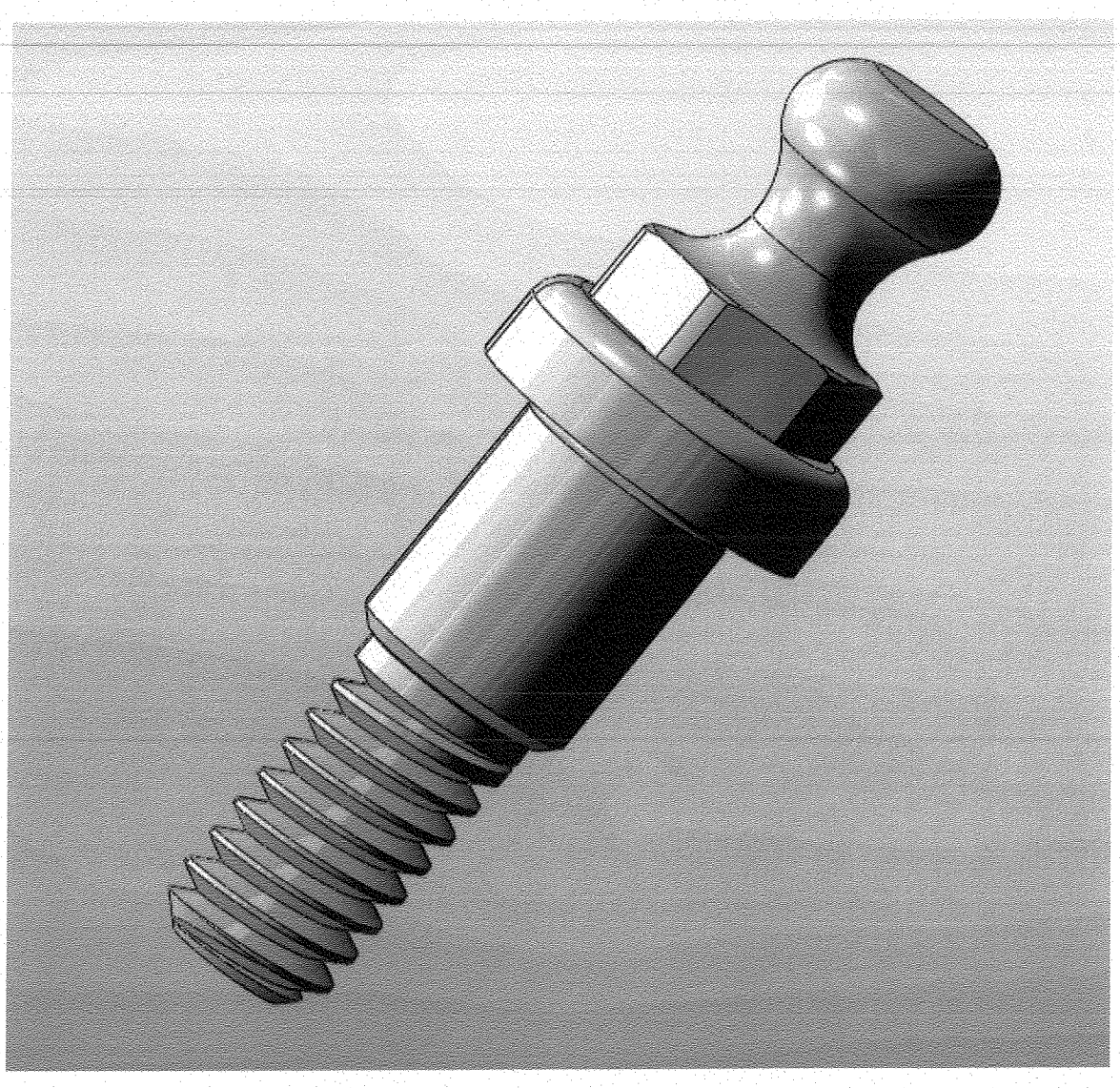
MR Safety: The ORA Implant Abutments are manufactured from a **non-ferromagnetic** material: 6AL-4V ELI titanium.

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**.

P/N	Description
(b)(4)	

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

SECTION 6

DEVICE DRAWINGS

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

(b)(4) Engineering Drawings

(b)(4) Engineering Drawings

(b)(4) Engineering Drawings

(b)(4) Engineering Drawings

(b)(4) Engineering Drawings

(b)(4) Engineering Drawings

(b)(4) Engineering Drawings

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(b)(4) Engineering Drawings

(b)(4) Engineering Drawings

(b)(4) Engineering Drawings

(b)(4) Engineering Drawings

(b)(4) Engineering Drawings

(b)(4) Engineering Drawings

(b)(4) Engineering Drawings

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) was performed to ensure full compatibility.

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

Substantial Equivalence Comparison

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
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 Connecting principle to overdenture: Retentive system Cleaning procedures for patient: Common procedure for oral hygiene Patient handling: Common cleaning and insertion of denture	Abutment Implant connection: Screw fixation Connecting principle to overdenture: Retentive system Cleaning procedures for patient: Common procedure for oral hygiene Patient handling: Common cleaning and insertion of denture	Abutment Implant connection: Screw fixation Connecting principle to overdenture: Retentive system Cleaning procedures for patient: Common procedure for oral hygiene 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

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)

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

SECTION 9

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.**

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.	Product Description
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]
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904692	ORA 3.0MM [AK]
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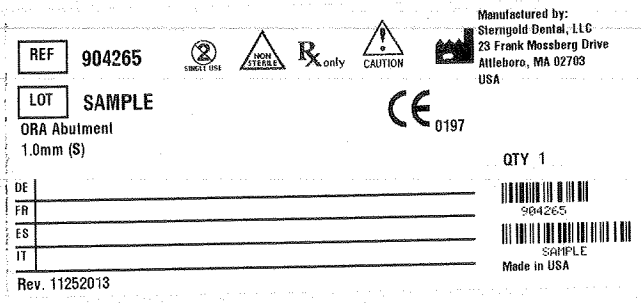
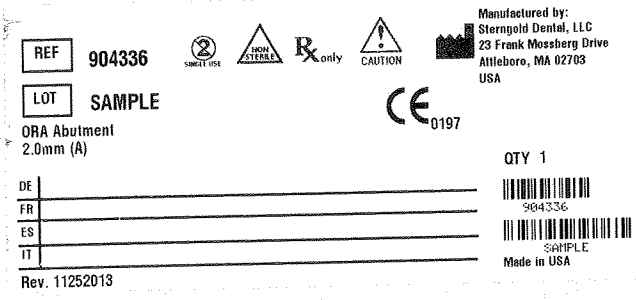
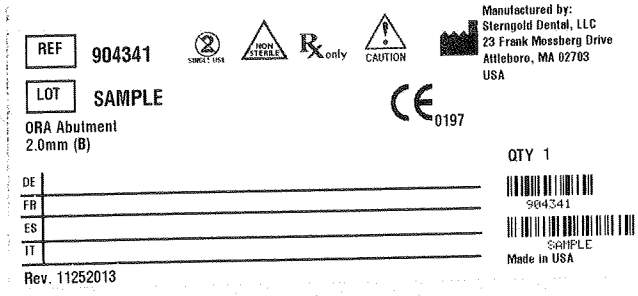
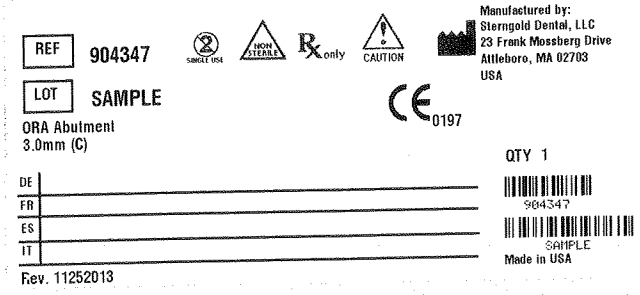
904698	ORA 4.0MM [BF]
904699	ORA 5.0MM [BF]

Proposed Device Labeling

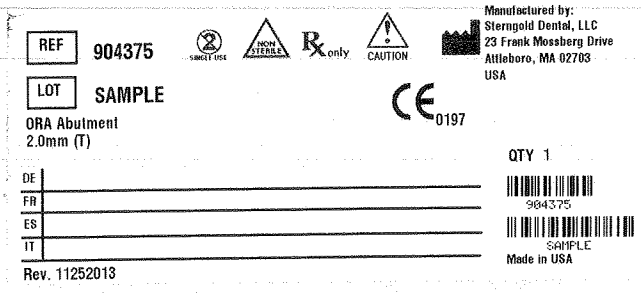


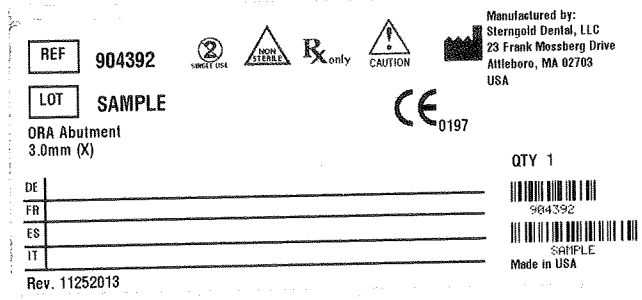


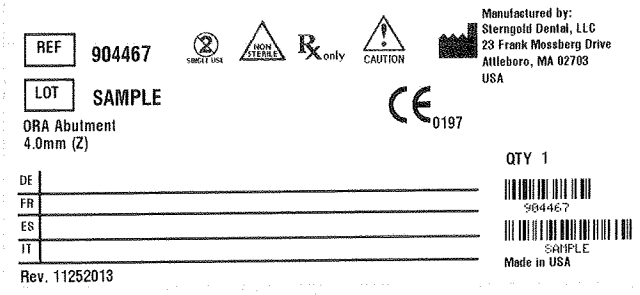


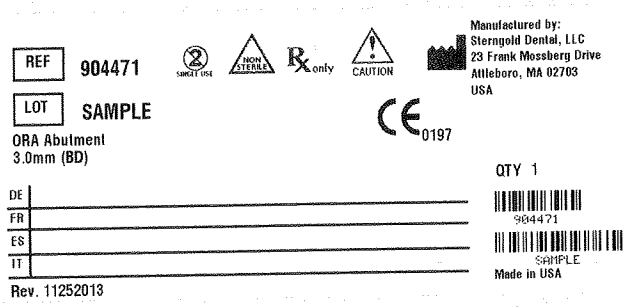


Proposed Device Labeling

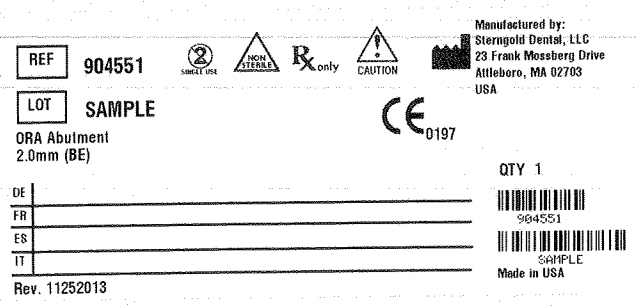


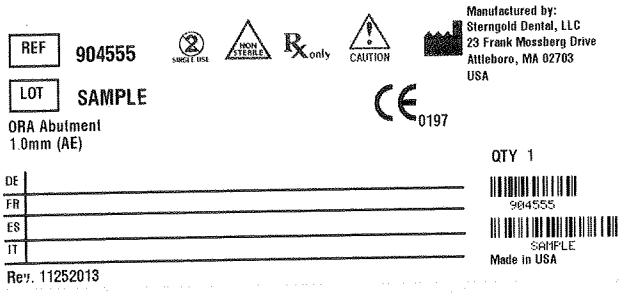


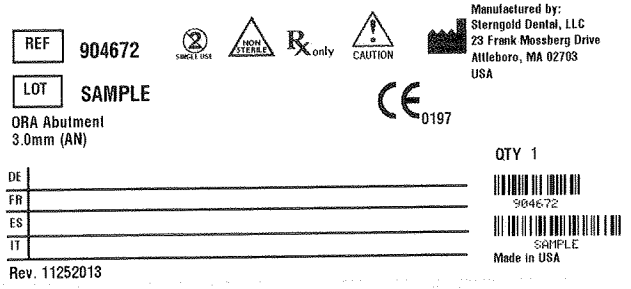


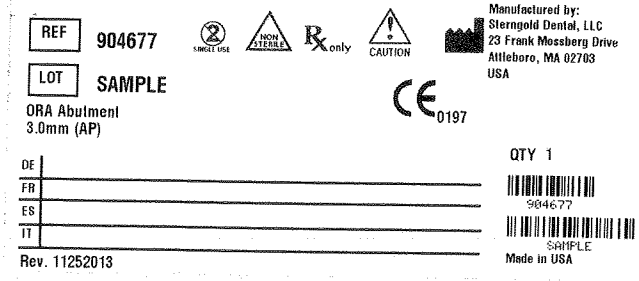


Proposed Device Labeling

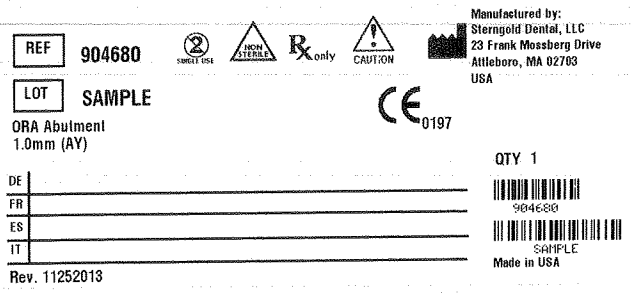


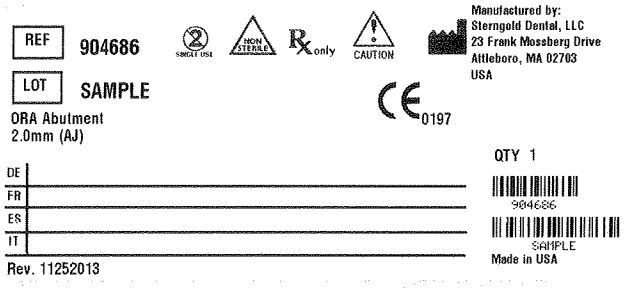


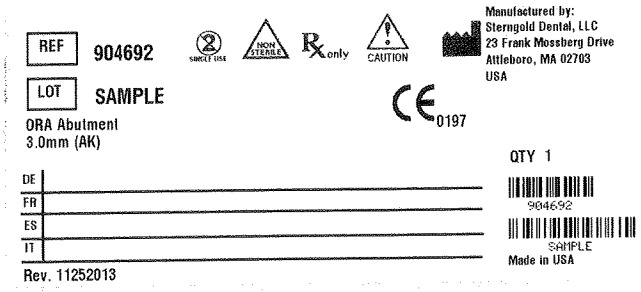


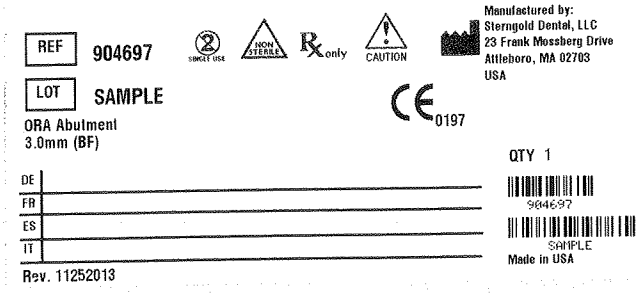


Proposed Device Labeling





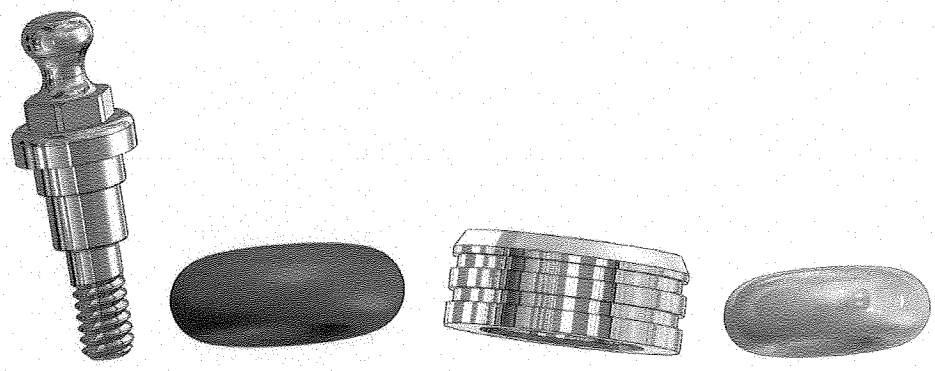




ORA Implant Abutment System

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		Benefits
Made for most popular implants	→	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®

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

SECTION 10

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 (b)(4) paper and (b)(4) (b)(4) (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

(b)(4) [redacted]

Validation of (b)(4) **Process:**

(b)(4) [redacted]

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

(b)(4) Specifications

[redacted]

ATTACHMENT G

TRUTHFUL AND ACCURATE STATEMENT

SECTION 11

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

SECTION 12

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 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™	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™, 3.75 Swede-Vent™ Conical Neck CST, 3.75 Swede-Vent™ Standard, 4.0 Swede-Vent™ Standard, 4.0 Bio-Vent® X™, 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™ (4.8 platform), 4.8 Tapered Swiss Plus™ 4.1 Straight Swiss Plus™, 4.8 Straight Swiss Plus™
Zimmer (Calcitek®, Centerpulse)	3.75 ThreadLoc™
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 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.

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

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

Label Symbol	Used For	Symbol	Used For
	Do not reuse		Symbol for Non-Sterile
	Catalog number		Batch code
	Manufacturer		Caution, consult accompanying documents
	Symbol for "Use by Prescription only"		Symbol for "European Conformity"
	Authorized representative in the European Community		

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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. 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.

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

TYPE OF 510(K) SUBMISSION

☐ Traditional ☐ Special ☒ Abbreviated

STANDARD TITLE [1]

ASTM F136-12a Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI Alloy for Surgical Implant App....

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# 8-341	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
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]

[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 assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] 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 www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
ASTM F136-12A Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI Alloy for Surgical Implant App....

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
B and I	Device Description and 510k Summary	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
All sections of this standard are applicable and have been met for conformance

DESCRIPTION
Product classification is 4.4 - Bar. Devices manufactured and certified to this standard

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

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

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

TYPE OF 510(K) SUBMISSION

☐ Traditional ☐ Special ☒ Abbreviated

STANDARD TITLE [1]

AAMI/ANSI/ISO 15223-1: 2012 Medical Devices-Symbols to be used with medical device labels, labeling and .....

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2] ?	☒	☐
FDA Recognition number [3]	# 5-73	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5] ?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
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]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

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[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.

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[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

PSC Graphics (301) 443-6740 EF

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

AAMI/ANSI/ISO 15223-1: 2012 Medical Devices-Symbols to be used with medical device labels, labeling and .....

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
E	Proposed Device draft labeling	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

All sections of this standard are applicable and have been met for cinformance.

DESCRIPTION

Device labeling was designed and developed in accordance with this standard, and it meets all the requirements.

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

◆ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

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Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☐ Traditional ☐ Special ☒ Abbreviated

STANDARD TITLE [1]

AAMI/ANSI/ISO 10993-1:2009, Biological evaluation of medical devices -Part 1: Evaluation and testing within a risk management.

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# 2-156	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
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]

[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 assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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PSC Graphics (301) 443-6740 EF

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

AAMI/ANSI/ISO 10993-1:2009, Biological evaluation of medical devices -Part 1: Evaluation and testing within a risk management.

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
F	Packaging, Sterilization and Pyrogenicity	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

◆ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

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Office of Chief Information Officer
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Rockville, MD 20850

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Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

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TYPE OF 510(K) SUBMISSION

☐ Traditional ☐ Special ☒ Abbreviated

STANDARD TITLE [1]

AAMI/ANSI/ISO 10993-5:2009, Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity.

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# 2-153	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
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]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

AAMI/ANSI/ISO 10993-5:2009, Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity.

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
F	Packaging, Sterilization and Pyrogenicity	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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TYPE OF 510(K) SUBMISSION

☐ Traditional ☐ Special ☒ Abbreviated

STANDARD TITLE [1]

ASTM F2459-12 Standard Test Method for Extracting Residue from Metallic Medical Components and Quantifying .....

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2] ?	☒	☐
FDA Recognition number [3]	# 8-334	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5] ?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
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If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
ASTM F2459-12 Standard Test Method for Extracting Residue from Metallic Medical Components and Quantifying .....

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
F	Packaging, Sterilization and Pyrogenicity	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

☐ Traditional ☐ Special ☒ Abbreviated

STANDARD TITLE [1]

(b)(4) [redacted]

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# (b)(4) [redacted]	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
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Title of guidance: _____

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[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

(b)(4)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
F	Packaging, Sterilization and Pyrogenicity	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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STANDARD TITLE [1]

(b)(4) [redacted]

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Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# (b)(4) [redacted]	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
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Title of guidance: _____

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

(b)(4) [redacted]

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
F	Packaging, Sterilization and Pyrogenicity	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

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K133791/S001

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

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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

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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

510K RTA Checklist Responses

K133791 ORA Abutment System

(b)(4) Deficiencies

[redacted]

(b)(4) Deficiencies

[redacted]

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

INDICATIONS FOR USE STATEMENT

SECTION 2

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, 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.O 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™	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™, 3.75 Swede-Vent™ Conical Neck CST, 3.75 Swede-Vent™ Standard, 4.0 Swede-Vent™ Standard, 4.0 Bio-Vent® X™, 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™ (4.8 platform), 4.8 Tapered Swiss Plus™ 4.1 Straight Swiss Plus™, 4.8 Straight Swiss Plus™
Zimmer (Calcitek®, Centerpulse)	3.75 ThreadLoc™
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 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

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

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)

COVER LETTER

SECTION 3

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 *The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications."*

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

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.
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.

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 [AN]	Nobel Replace WP, Nobel Replace Select WP, NobelSpeedy Replace WP, Implant Direct 5.0 RePlant, BlueSky Bio 5.0 Trilobe
Nobel Biocare [AP]	Nobel Conical Connection RP, Blue Sky Bio Max
Nobel Biocare [AY]	Nobel Conical Connection NP
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 [BF]	Zimmer TSV 5.7mm, Implant Direct Legacy 5.7, BioHorizon 5.7

Nobel Biocare Brånemark System [A]	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 [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 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™ (3.3 and 4.0 fixtures)
3i Implant Inovations [A]	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,
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™, 4.0 OSSEOTITE® NTCertain™, 4.O 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™, 3.75 Swede-Vent™ Conical Neck CST, 3.75 Swede-Vent™ Standard, 4.0 Swede-Vent™ Standard, 4.0 Bio-Vent® X™,
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™ (4.8 platform), 4.8 Tapered Swiss Plus™ ,4.1 Straight Swiss Plus™ , 4.8 Straight Swiss Plus™
Zimmer (Calcitek®, Centerpulse) [A]	3.75 ThreadLocTM
Straumann [S]	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 [A]	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 [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 [C]	5.0mm Internal Hex
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 [A]	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

Operation Mechanism

(b)(4)

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 - (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.
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.

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.	Product Description
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-Ring
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, 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.O 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™	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™, 3.75 Swede-Vent™ Conical Neck CST, 3.75 Swede-Vent™ Standard, 4.0 Swede-Vent™ Standard, 4.0 Bio-Vent® X™, 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™ (4.8 platform), 4.8 Tapered Swiss Plus™ 4.1 Straight Swiss Plus™, 4.8 Straight Swiss Plus™
Zimmer (Calcitek®, Centerpulse)	3.75 ThreadLoc™
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 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 (b)(4) Manufacturer's implants were purchased and (b)(4) was performed to ensure full compatibility.

Continuous compatibility with manufacturer's implants indicated on this application and respective abutments will be verified every (b)(4) 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
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 Connecting principle to overdenture: Retentive system Cleaning procedures for patient: Common procedure for oral hygiene Patient handling: Common cleaning and insertion of denture	Abutment Implant connection: Screw fixation Connecting principle to overdenture: Retentive system Cleaning procedures for patient: Common procedure for oral hygiene Patient handling: Common cleaning and insertion of denture	Abutment Implant connection: Screw fixation Connecting principle to overdenture: Retentive system Cleaning procedures for patient: Common procedure for oral hygiene 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

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 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.O 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™	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™, 3.75 Swede-Vent™ Conical Neck CST, 3.75 Swede-Vent™ Standard, 4.0 Swede-Vent™ Standard, 4.0 Bio-Vent® X™, 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™ (4.8 platform), 4.8 Tapered Swiss Plus™ 4.1 Straight Swiss Plus™, 4.8 Straight Swiss Plus™
Zimmer (Calcitek®, Centerpulse)	3.75 ThreadLoc™
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 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 (≥ 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

Sterilization

(b)(4)

[redacted]

Validation of (b)(4) **Process:**

(b)(4)

[redacted]

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

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 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	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 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™	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™, 3.75 Swede-Vent™ Conical Neck CST, 3.75 Swede-Vent™ Standard, 4.0 Swede-Vent™ Standard, 4.0 Bio-Vent® X™, 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), 4.3 Bio-Vent® (4.5 head), 4.7 Screw-Vent® (4.5 head), 5.3 Core-Vent® (4.5 head), 3.7 Tapered Swiss Plus™ (4.8 platform), 4.8 Tapered Swiss Plus™ 4.1 Straight Swiss Plus™, 4.8 Straight Swiss Plus™
Zimmer (Calcitek®, Centerpulse)	3.75 ThreadLoc™
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 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
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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.

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.

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

Label Symbol	Used For	Symbol	Used For
	Do not reuse		Symbol for Non-Sterile
	Catalog number		Batch code
	Manufacturer		Caution, consult accompanying documents
	Symbol for "Use by Prescription only"		Symbol for "European Conformity"
	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.

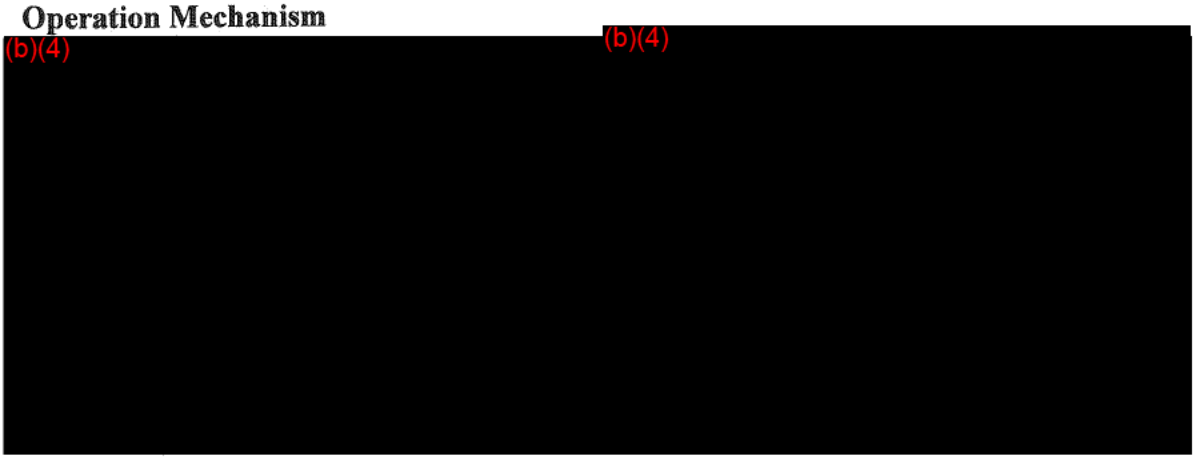
The retaining ring (metal housing) comes with the red o-ring (which is a firm rubber) inside. The retaining ring (metal housing) with the red o-ring is pushed over the wide part of the ball until seated. The stiffness of the red o-ring holds the housing in position. Any exposed areas of the abutment 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.

Operation Mechanism

(b)(4)



(b)(4)

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 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.O 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™	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™, 3.75 Swede-Vent™ Conical Neck CST, 3.75 Swede-Vent™ Standard, 4.0 Swede-Vent™ Standard, 4.0 Bio-Vent® X™, 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™ (4.8 platform), 4.8 Tapered Swiss Plus™ 4.1 Straight Swiss Plus™, 4.8 Straight Swiss Plus™
Zimmer (Calcitek®, Centerpulse)	3.75 ThreadLoc™
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 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.

The material of the O-Rings is:

- Red Processing O-Ring - (b)(4) [redacted]
- White Final O-Ring – (b)(4) [redacted]

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.

PROJECT (b)(4)
(b)(4)

Verification and Validation of the
(b)(4)

TEST REPORT

(b)(6)

Quality Manager

(b)(6)

Director of Regulatory Affairs

(b)(6)

Design Engineer

Date: NOV 15, 2013

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

Addendum to Product Information - Section F of Form FDA 3514

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

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

K133791/S002

Sterngold®

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

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Cust. Serv: (800) 243-9942
Fax: (508) 226-5473
Toll Free Fax: (800) 531-2685

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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

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http://www.sterngold.com

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Cust. Serv: (800) 243-9942
Fax: (508) 226-5473
Toll Free Fax: (800) 531-2685

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

To: "Giles, Lauren" <Lauren.Giles@fda.hhs.gov>,
Cc:
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:

(b)(4)

[redacted]

(b)(4) Deficiencies

(b)(4) Deficiencies

(b)(4) Deficiencies

[redacted]

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(l), 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(l), 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(l) 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 [AN]	Nobel Replace WP, Nobel Replace Select WP, NobelSpeedy Replace WP, Implant Direct 5.0 RePlant, BlueSky Bio 5.0 Trilobe
Nobel Biocare [AP]	Nobel Conical Connection RP, Blue Sky Bio Max
Nobel Biocare [AY]	Nobel Conical Connection NP
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 [BF]	Zimmer TSV 5.7mm, Implant Direct Legacy 5.7, BioHorizon 5.7

Nobel Biocare Brånemark System [A]	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 [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 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™ (3.3 and 4.0 fixtures)
3i Implant Inovations [A]	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,
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™, 4.0 OSSEOTITE® NTCertain™, 4.O 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™, 3.75 Swede-Vent™ Conical Neck CST, 3.75 Swede-Vent™ Standard, 4.0 Swede-Vent™ Standard, 4.0 Bio-Vent® X™,
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™ (4.8 platform), 4.8 Tapered Swiss Plus™ ,4.1 Straight Swiss Plus™ , 4.8 Straight Swiss Plus™
Zimmer (Calcitek®, Centerpulse) [A]	3.75 ThreadLocTM
Straumann [S]	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 [A]	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 [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 [C]	5.0mm Internal Hex
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 [A]	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

Operation Mechanism

(b)(4)

3

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) (b)(4)
- White Final O-Ring – (b)(4) (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.

Application testing consisted of (b)(4) Manufacturer's implants were purchased and (b)(4) was performed to ensure full compatibility.

Continuous compatibility with manufacturer's implants indicated on this application and respective abutments will be verified every (b)(4) 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, 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 Connecting principle to overdenture: Retentive system Cleaning procedures for patient: Common procedure for oral hygiene Patient handling: Common cleaning and insertion of denture	Abutment Implant connection: Screw fixation Connecting principle to overdenture: Retentive system Cleaning procedures for patient: Common procedure for oral hygiene Patient handling: Common cleaning and insertion of denture	Abutment Implant connection: Screw fixation Connecting principle to overdenture: Retentive system Cleaning procedures for patient: Common procedure for oral hygiene 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

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) Testing

Tolerance Analysis

(b)(4)

[redacted]

(b)(4) Tolerance Analysis

(b)(4)

(b)(4) Tolerance Analysis

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Tolerance Analysis

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Tolerance Analysis

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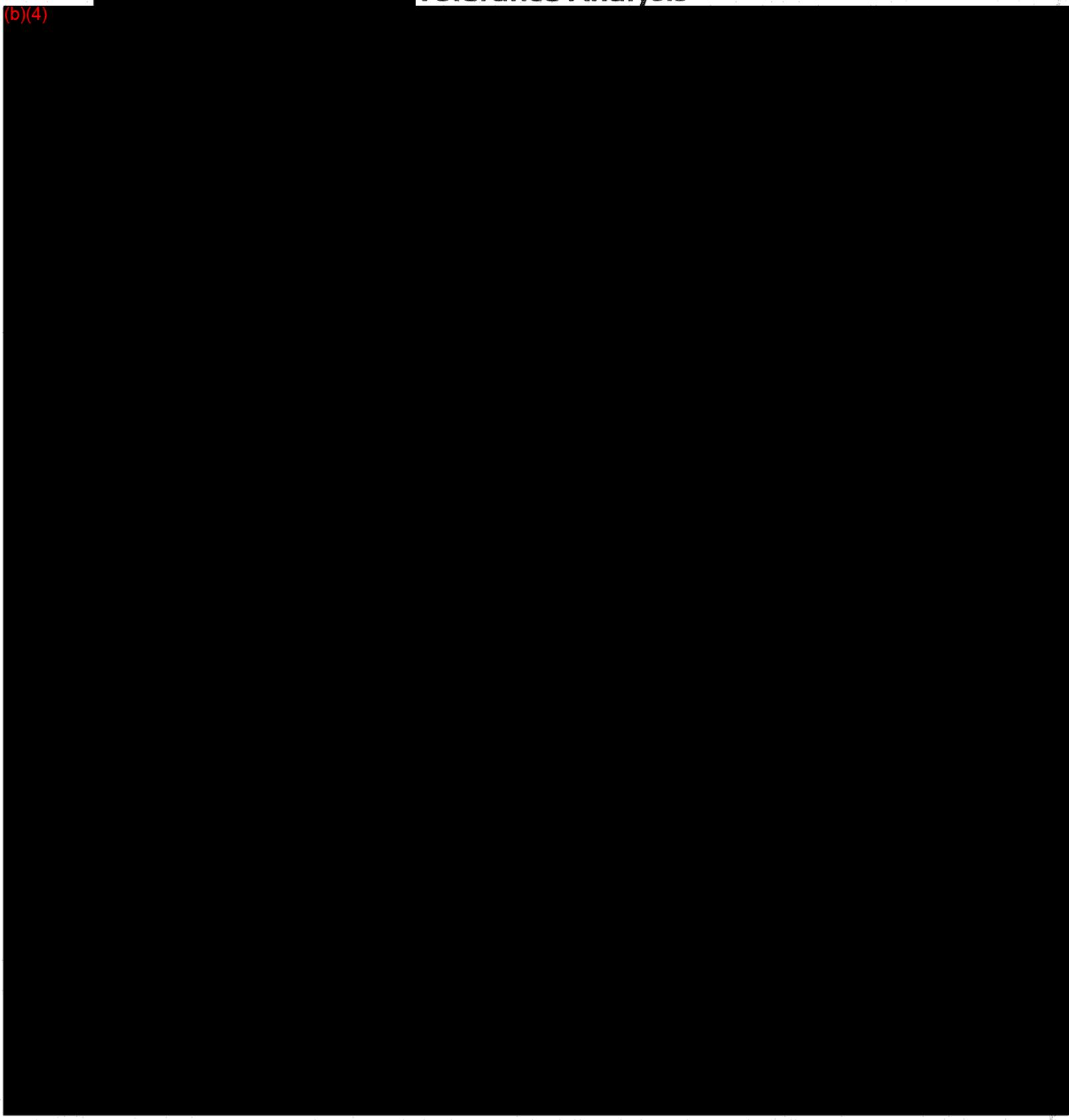

Tolerance Analysis

(b)(4)

(b)(4) Tolerance Analysis

(b)(4)

(b)(4) Testing

Tolerance Analysis

(b)(4)

[redacted]

(b)(4) [redacted] **Tolerance Analysis**

(b)(4) [redacted]

Tolerance Analysis

(b)(4)

Sterilization

(b)(4)

[redacted]

Validation of (b)(4) Process:

(b)(4)

[redacted]

25

(b)(4)

[redacted]

(b)(4)

[redacted]

Sterilization Validation

(b)(4)

[redacted]

ATTACHMENT H

INSTRUCTIONS FOR USE

SECTION 12

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 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	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 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.O 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™	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™, 3.75 Swede-Vent™ Conical Neck CST, 3.75 Swede-Vent™ Standard, 4.0 Swede-Vent™ Standard, 4.0 Bio-Vent® X™, 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™ (4.8 platform), 4.8 Tapered Swiss Plus™ 4.1 Straight Swiss Plus™, 4.8 Straight Swiss Plus™
Zimmer (Calcitek®, Centerpulse)	3.75 ThreadLoc™
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 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
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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
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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.

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

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.

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.

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 (BIs, CIs, 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^{-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: 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 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.

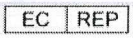
O-Ring Placement Procedure:
The retaining ring (metal housing) comes with the red o-ring (which is a firm rubber) inside. The retaining ring (metal housing) with the red o-ring is pushed over the wide part of the ball until seated. The stiffness of the red o-ring holds the housing in position. Any exposed 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.
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

Label Symbol	Used For	Symbol	Used For
	Do not reuse		Symbol for Non-Sterile
	Catalog number		Batch code
	Manufacturer		Caution, consult accompanying documents
	Symbol for "Use by Prescription only"		Symbol for "European Conformity"
	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, 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." [redacted] 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.
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.