K130408



# 510(k) Summary

JUL 0 1 2013

**Trade Name:** **ERA® Micro 23 ° and 30° Female Abutment**

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

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

**Device Generic 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)

**Predicate Devices:**
The ERA® Micro 23 ° and 30° Female abutment is substantially equivalent to other currently marketed devices that have been cleared by FDA through the 510(k) Premarket Notification process, including the Stern ERA® Alignment Correction Abutments (5°, 11°, and 17°), and the Osseospeed™ Angled Abutment EV.

| | |
|---|---|
| K921010 | Stern ERA® Alignment Correction Implant Abutments |
| K121810 | Osseospeed™ Angled Abutment EV |
| K023580 | Sterngold Acid Etch Dental Implant System |

**Product Description:**
The ERA® Micro 23° and 30° Female Abutment is a prosthetic component intended to facilitate functional parallelism of the ERA® Females despite diverging implants during prosthetic rehabilitation. It is intended to be used in conjunction with the Sterngold Acid Etch Dental Implant System in the maxillary and/or mandibular arch to provide support for overdentures for partially and fully edentulous patients.
It is intended to support single and multiple tooth prostheses in the mandible or maxilla.
It is provided in a 3.22mm diameter and two angles (23° and 30°).

These devices have a two piece design configuration; the two-piece assembly consists of a straight base which has a screw post that gets engaged into the internal threading of the dental implant and an angled female, which allows the user to achieve functional parallelism with divergent implants.

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**Material Composition:**
The ERA® Micro 23° and 30° Female Abutment is manufactured from the same materials as the predicate devices. The specification for the material used to manufacture the ERA® Micro 23° and 30° Female is 6AL-4V ELI titanium classified as ASTM F136-11.
The female receptacle of the ERA® Micro 23° and 30° female abutment, which resides at or above the gingival crest and couples with the Stern ERA System male attachments, is coated with titanium nitride (TiN), which has been cleared under K921010. No coating is applied to snap-in post of the angled female insert or the bases.

**Packaging:**
These devices are supplied non-sterile in a sealed pouch including instructions for use. Instructions for Use indicate recommended method of sterilization prior to use. These parts are packaged individually.

**Indications for Use:**
The ERA® Micro 23° and 30° Females are intended to be used as a retention device in conjunction with the Sterngold Acid Etch Dental Implant System in the maxillary and/or mandibular arch to provide support for overdentures for partially and fully edentulous patients.

**Substantial Equivalence:**
The proposed ERA® Micro 23° and 30° Females are substantially equivalent to other currently marketed devices that have been cleared by FDA through the 510(k) Premarket Notification process.

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|---|---|
| K921010 | Stern ERA® Alignment Correction Abutments |
| K121810 | Osseospeed™ Angled Abutment EV |
| K023580 | Sterngold Acid Etch Dental Implant System |

**Technological Characteristics:**
The proposed ERA® Micro 23 ° and 30° Female Abutments are substantially equivalent and have the same technological characteristics as the predicate devices. They have similar design characteristics and are manufactured from the same or similar materials (Titanium Alloy 6AL-4V ELI ASTM F136-11).
They have the same intended use and are multi-unit screw-retained dental implant abutments as the predicate devices.
The differences between the components included in this submission and their predicate devise pose no new or additional issues of safety or effectiveness.

**Performance Testing:**
Performance testing was performed following "Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments." and ISO 14801:2007. Performance testing demonstrated that the device performs according to its intended use.

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Fatigue testing was conducted in accordance with ISO 14801:2007 Dentistry – Implants-Dynamic fatigue test for endosseous dental implants. The testing was conducted on a 30° angled female abutment and a small diameter (3.75mm) Sterngold Acid Etch Dental Implant finished product. This was determined to be the worst case scenario, largest angle, smallest diameter implant.
Samples were tested with the implants long axis at 40° angle of correction.
The hemispherical cap to fix the moment arm at 11mm, ensuring that no lateral constraint occurs is represented by a white ERA male component, which represents how this device is intended to be used.
Fatigue testing demonstrated that the ERA® Micro 23° and 30° Females have sufficient mechanical strength and resistance to fatigue for the intended clinical application and that they are substantially equivalent to the listed predicate devices.

**Conclusion:**

Based on our analysis, the proposed device is substantially equivalent in intended use, material, design and performance to its predicate devices.

- has the same intended use
- uses same or similar indications for use
- incorporates the same basic design
- incorporates the same or very similar materials

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

July 1, 2013

Ms. Maria Rao
Director of Regulatory Affairs
Sterngold Dental, Limited Liability Company
23 Frank Mossberg Drive
ATTLEBORO MA 02703

Re: K130408
Trade/Device Name: ERA® Micro 23° and 30° Female Abutment
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: May 22, 2013
Received: May 29, 2013

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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.htmfor 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,

Kwame O. Ulmer -S

Kwame Ulmer, M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known): K130409

Device Name: **ERA® Micro 23° and 30° Female Abutments**

**Indications for Use:**

The ERA® Micro 23° and 30° Females are intended to be used as a retention device in conjunction with the Sterngold Acid Etch Dental Implant System in the maxillary and/or mandibular arch to provide support for overdentures for partially and fully edentulous patients.

(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 Subpart D) AND/OR Over-the-Counter Use ____ (21 CFR 807 Subpart D)

Sheena A. Green -S
2013.07.01 11:21:24 -04'00'
for M. Susan Runner, DDS, MA

**(Division Sign-Off)**
**Division of Anesthesiology, General Hospital Infection Control, Dental Devices**

**510(k) Number:** K130408