K113539

MAY 3 2013

Traditional 510 (k) Summary:

REVOIS® PRO Implant System

1. SUBMISSION INFORMATION

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Date created:	April 19th 2013
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2. DEVICE IDENTIFICATION

Proprietary Name:	REVOIS® PRO Implant System
Common Name:	Dental implant system, dental implant abutment
Classification Name:	Endosseous Dental Implant, root-form and Endosseous dental implant abutment
Classification:	Class II, Special Controls
Classification regulation Number:	21CFR 872.3640 21CFR 872.3630
Product Code: Subsequent Product Code:	DZA, Endosseous implant NHA, Endosseous implant abutment

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3. PREDICATE DEVICES

REVOIS® Implant System: K063106

4. DESCRIPTION OF THE DEVICE

The REVOIS® PRO Implant System is a development of the former REVOIS® Implant System.
The REVOIS® PRO Implant System is a self-contained, modular dental implant system for placement into the jaw bone (upper or lower jaw bone) to support prosthetic devices for dental restoration. The system is designed for one-stage or two-stage surgical procedures.
The REVOIS® PRO Implant System is composed of a titanium screw type cylindrical implant. It is a screw form implant with cylindrical thread and a progressive thread near the apex. The double thread of the implant body is contiguous with the triple thread (fine thread) at the implant neck. Together with the conical implant body of the REVOIS®: PRO implant, the progressive thread makes sure that the implant is well anchored in the host bone of the alveolar crest. The incremental pitch of the thread upwards evenly distributes the forces so that implants heal well and can be loaded immediately.
The implant system is delivered in a sterile insert blister and comprises an implant, an impression abutment, an impression screw and a cover screw (sterile packed as a set in a blister packaging). The impression screw serves as a connector between impression abutment and implant so that the pre-assembled parts fit tightly into the inlay for sterility reasons. The system offers implants in various diameters and lengths (3.8; 4.3; 5.0 mm diameter; 9; 11; 13; 15 mm lengths). For ease of identification the implants are color coded according to diameter.

The dental abutment portions of the REVOIS®: PRO implant system include several abutments described subsequently:

- Healing Abutments of diameter 4.4 mm and 5.2 mm in height 2 mm, 3mm and 5 mm each, made of Titanium Grade 5
- Standard abutment (incl. retaining screw) of diameter 4,4 mm and 5.2 mm in height 5 mm and 7 mm each, made of Titanium Grade 5
- Individual aesthetic abutment of diameter 4,4 mm, made of CERAMICOR®, a gold- platinium alloy
- Impression abutment, multi (pre-mounted with impression screw) made of Titanium Grade 5
- Impression abutment open tray of diameter 4.4 mm, made of Titanium Grade 5
- Locator® abutment, made of Titanium Grade 5
- Locator® Replacement set, consists of several components made of plastic and Titanium Grade 5
- Locator® impression coping, made of the Aluminium Alloy 6061
- Dalbo® ball attachment of diameter 4.4 mm and in height 3 mm and 5mm, made of Titanium Grade 5

The REVOIS® PRO Implant System is provided with a variety of prosthetic components and tool which are definitely 510(K)-exempt or still cleared by the submission K063106.

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The main components of the implant system are made of Grade IV or Grade V Titanium (implant, abutment). The materials comply with the ASTM standards ASTM F067 (implant) and ASTM F0136-2a (abutment). The implant surface is blasted with luminium oxide particles (Corundum) and then acid-etched for micro-roughness.
The REVOIS® PRO titanium implant is sterile packed for single use only. The sterility is indicated by the color on the sterility indicator attached to the inner Tyvek® foil.

5. STATEMENT OF INTENDED USE

The basis for the substantial equivalence of the REVOIS® PRO Implant System is the following:

The REVOIS® PRO Implant System is an implant system recommended for surgical placement in the edentulous or partly edentulous jaw bone (upper and lower jaw bone) to create support for prosthetic devices such as single artificial teeth, fixed or removable bridges, or dentures.

The titanium implant can be applied either in a one-stage surgical procedure with immediate loading (with good primary stability and appropriate occlusal loading) in a two-stage surgical procedure (after osseointegration of the implant).

6. STATEMENT OF TECHNOLOGICAL COMPARISON

The REVOIS® PRO Implant System provides state-of-the art implant technology and options that are comparable to the technology of the predicate devices. The innovative design (cylindrical form of implant, double thread of the implant body turns into a fine thread in the neck of the implant) and pre-assembled version of implant, abutment (which fits for all implants and implant diameters) offers easy handling for the dentist/surgeon by reducing the number of components needed for successful placement of the implant, while ensuring precision and stability. The geometric design of the implant is with cylindrical shape and rounded apex.
Compared with the predecessor REVOIS® Implant System, the screw thread of the REVOIS® PRO Implant System covers only about two thirds of the implant, the upper third of the extension of the implant is covered by the mentioned fine thread. The proximal end of the thread is a circumferential crease.

The stability of the implant body and the thread of the REVOIS®: PRO implant system was tested in non-clinical performance testing as Fatigue Testing with mounted standard abutment according to ISO 14801 and Bench Testing with Animal Model. All the tests were also performed with the precursor system REVOIS® with comparable results. The critical appreciation within the clinical assessment was done with the following non-clinical and clinical testing data to support this submission: FRIATEC, 1998; Cia et al., 2003; Striezel et al., 1998; Mathew et al., 2000; Jonas et al., 2001; Steigenga et al., 2004; Steigenga et al., 2003; Steigenga et al., 1999; Jalbout et al., 2004; Jividen et al., 2000; Massaro et al., 2002; Gross et al., 1998; Burgess et al. 1999; Chen et al., 2004; Elagli et al., 1989; Hemmerle et al., 1996; Pohler, 2000; Valesco- Ortega et al., 2010;

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Zaffe et al., 2003; Guizzardi et al., 2004; Shirakura et al., 2003 Esposito et al., 1998; Elagli et al., 1992; Rosengren et al., 2002; Sicilia A. et al., 2008; Kumazawa et al., 2002; Assad et al., 1999.

Additional substantial equivalence results in equivalence to a variety of currently marketed and cleared dental implants or implant systems, especially the REVOIS® Implant System.
Both systems feature root form, screw type, endosseous implants made of titanium, and corresponding 510(K)-exempted tools, instruments and partly 510(K)-exempted accessories. Color coding of components is used in all systems compared for this submission to simplify identification and prevent mix-up of non-coordinating parts. The systems are essentially similar regarding intended use, indications, target population, anatomical sites, implant diameters and lengths, implant to abutment connection, materials used and performance aspects. In addition both systems presented have a treated, roughened surface and tapered parts of the implant bodies. A one-stage or two-stage surgical procedure is possible with the REVOIS® PRO system and the predicate device.

The differences outlined in the SE comparison evaluation/discussion between the REVOIS® system and the predicate device, do not affect the safety or effectiveness of the REVOIS® PRO Implant System.

The REVOIS® system is indeed similar or equivalent, in most compared specifications (Classification, Classification Product Code, Intended Use, Indications for Use, Target population, Anatomical sites, Materials, Implant surface, Implant to abutment connection, Implant diameters, Implant lengths, Identification, Biocompatibility, Compatibility with the environment and other devices, Where used, Human factors, Design, Thread design, Performance, Technology, Standards met, Sterility, Mechanical safety and Chemical safety) regarding design and performance even identical enough, to serve as predicates, but the REVOIS® PRO Implant System does have certain advantages of design and technology.

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

May 3, 2013

Mr. Christopher Wahl
Riemser Arzneimittel AG
An der Wiek 7
Greifswald-Insel Riems
Mecklenburg-Vorpommern 17493
GERMANY

Re: K113539
Trade/Device Name: REVOIS® PRO Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: April 25, 2013
Received: April 29, 2013

Dear Mr. Wahl:

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,

Kwame O. Ulmer -S for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K113539

Device Name: REVOIS® PRO Implant System

Indications for Use:

REVOIS PRO Implant System is an implant system recommended for surgical placement in the edentulous or partially edentulous jaw bone (upper or lower jaw bone) to create support for prosthetic devices such as single artificial teeth, fixed or removable bridges, or dentures.

The titanium implant can be applied either in a one-stage surgical procedure with immediate loading (with good primary stability and appropriate occlusal loading) or in a two-stage surgical procedure (after osseointegration of the implant).

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S. Runner -S

Digitally signed by Mary S. Runner -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Mary S. Runner -S, 0.9.2342.19200300.100.1.1=1300087950
Date: 2013.05.03 15:35:11 -04'00'

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

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