zimmer
dental

Zimmer Dental
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510k No.: K111852

AUG 11 2011

Special 510(k): Device Modification
PRE-MARKET NOTIFICATION 510(k)
510(k) SUMMARY (21CFR807.92(a))

1. Submitter's Information:

Name:	Zimmer Dental Inc.
Address:	1900 Aston Ave. Carlsbad, CA 92008
Phone:	760-929-4300
Contact:	Melissa Burbage
Date Prepared:	June 28, 2011

2. Device Name:

Trade Name:	Anodized Healing Collar
Regulation Number:	872.3630
Classification Code:	NHA

3. Predicate Device(s):

Trade Name:	Paragon Implant System (now known as Tapered Screw-Vent System)
510(k) No:	K953101
Regulation Number:	872.3640
Classification Code:	DZE

4. Device Description:

The healing collar is designed to form the soft tissue during the healing period before a final restoration is placed. The device is threaded onto the implant immediately after implant placement in a one-stage protocol. In a two-stage protocol, the healing collar is placed on the implant following the bone healing period. The soft tissue is sutured around the healing collar and the device remains in the mouth until the soft tissue fully develops.

Depending on the needs of the patient, various healing collar sizes are available to interface with the implant and also to properly form the soft tissue. Healing collars are offered with three distinct implant platform diameters to accommodate for the different implant platform sizes. They are also available in differing cuff heights and emergence profile diameters to assist in forming the soft tissue. Because of the various

sizes available, certain features are being incorporated into the design to assist in identifying the healing collars visually:

1.) The bottom half of the healing collar will be colored according to the shade that defines its respective implant platform size.

2.) The top face will be etched with all size parameters related to the use of the healing collar: implant platform diameter, emergence profile diameter, cuff height.

5. Indications for Use:

The Healing Collar is used to assist in the forming of the soft tissue during healing before a final restoration is placed. The Healing Collar is for single use only.

6. Device Comparison:

The new device is equivalent in design with Healing Collar Predicate. The new device has an added manufacturing process of anodization to allow for color coding. The device dimensions specifications, material, implant interface, and function in the system remains the same as the Healing Collar Predicate Device.

7. Non-Clinical Testing:

Non-clinical testing was not performed. The Healing Collars are not load bearing components, they are placed out of occlusion and experience minimal mechanical forces. Since the design and function of the Anodized Healing Collars is equivalent to the existing Healing Collars, the mechanical properties of the material are sufficient for the function of the part. In addition, because the two part families are dimensionally identical, the Anodized Healing Collars will interface with mating components in the same manner as the current Healing Collars. Therefore, any loading conditions will remain the same and the Anodized Healing Collars do not present a new worst case when compared to the Healing Collars. As a result, mechanical testing is not necessary.

8. Clinical Testing

No clinical testing was performed. Non-clinical testing was used to support the decision of safety and effectiveness.

9. Conclusion

Based on our analysis, the device is substantially equivalent to the predicate and considers the new device is as safe and effective for its intended use and performs as well the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Melissa Burbage
Manager, Regulatory Affairs
Zimmer Dental, Incorporated
1900 Aston Avenue
Carlsbad, California 92008-7308

AUG 11 2011

Re: K111852
Trade/Device Name: Anodized Healing Collar
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: August 1, 2011
Received: August 2, 2011

Dear Ms. Burbage:

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.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,

for

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

Enclosure

zimmer dental

Indications for Use

510(k) Number (if known): K111852

Device Name: ***Anodized Healing Collar***

Indications For Use:

The Healing Collar is used to assist in the forming of the soft tissue during healing before a final restoration is placed. The Healing Collar is for single use only.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K111852