K132984

JAN 14 2014

510(K) SUMMARY (revised 12.11.2013)

SR Vivodent S, SR Orthotyp S, SR Ortholingual S

Contact: Donna Marie Hartnett, Director of QA/Regulatory Affairs

Company: Ivoclar Vivadent. 175 Pineview Drive, Amherst, NY 14228
(716) 691-0010

Date Prepared: December 11, 2013

Proprietary Name: SR Vivodent S, SR Orthotyp S, SR Ortholingual S

Classification Name: Denture, Plastic, Teeth (872.3590)

Predicate Devices: SR Vivodent PE, SR Orthotyp PE (K844349) and Phonares II (K120736)

Device Description: Preformed denture teeth used for total and partial dentures and implant-supported removable prostheses.

The predicate device to which SR Vivodent S, SR Orthotyp S, SR Ortholingual S have been compared is SR Vivodent PE, SR Orthotyp PE (K844349) and Phonares II (K120739). For this application, SR Vivodent S, SR Orthotyp S, SR Ortholingual S, has been compared to K844349 predicate with regard to chemical composition, performance data and indications for use. The subject device has also been compared to Phonares II (K120739) with regard to indications for use. The comparison shows that SR Vivodent S, SR Orthotyp S, SR Ortholingual S are substantially equivalent to the predicate devices.

Intended Use: Preformed denture teeth used for total and partial dentures and implant-supported removable prostheses.

Technological Characteristics: The device design, i.e. delivery form, and intended use of SR Vivodent S, SR Orthotyp S, SR Ortholingual S, and the predicate device are the same. The composition of the subject device has been modified from the predicate; however, there are no ingredients in the subject device which pose any new issues of safety and effectiveness.

Testing Summary: The Device has been tested in accordance with ISO 22112:2005 for Artificial denture teeth and it meets the requirements defined. The device was also tested in accordance with ISO 10477:2004 Polymer based crown & bridge materials for Flexural Strength, Water sorption and Solubility. Finally, the materials were tested using a Ball Indentation test according to DIN EN ISO 2039-1. Biocompatibility testing and evaluation was also carried out according to ISO 10993. The subject device is a PMMA denture tooth, the composition of which is well known and accepted as biocompatible in dentistry.

Conclusion: SR Vivodent S, SR Orthotyp S, SR Ortholingual S, is substantially equivalent to the predicate device.

Concurrence & Template History Page
[THIS PAGE IS INCLUDED IN IMAGE COPY ONLY]

Full Submission Number:

For Office of Compliance Contact Information:

http://insideportlets.fda.gov:9010/portal/page?_pageid=197,415881&_dad=portal&_schema=PORTAL&org=318

For Office of Surveillance and Biometrics Contact Information:

http://insideportlets.fda.gov:9010/portal/page?_pageid=197,415881&_dad=portal&_schema=PORTAL&org=423

Digital Signature Concurrence Table	
Reviewer Sign-Off	Myra Browne
Branch Chief Sign-Off	Susan Runner
Division Sign-Off	Kwame O=Ulmer-S 2014.01.14 13:36:24 -05'00'

Template Name: K1(A) – SE after 1996

Template History:

Date of Update	By	Description of Update
7/27/09	Brandi Stuart	Added Updates to Boiler Table
8/7/09	Brandi Stuart	Updated HFZ Table
1/11/10	Diane Garcia	Liability/Warranty sentence added at bottom of 1st page
10/4/11	M. McCabe Janicki	Removed IFU sheet and placed in Forms
9/25/12	Edwena Jones	Added digital signature format
12/12/12	M. McCabe Janicki	Added an extra line between letter signature block and the word "Enclosure". Also, added a missing digit in 4-digit extension on letterhead zip code: "002" should be "0002".
4/2/2013	M. McCabe Janicki	Edited sentence that starts "If you desire specific advice for your device on our labeling regulation (21 CFR Part 801)..." Replaced broken Compliance link with general link to DSMICA.
4/12/2013	Margaret McCabe Janicki	Fixed a typo: Paragraph 1, final sentence, "We remind you, however; that device labeling must be truthful..." Replaced incorrect semicolon with a comma.

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

January 14, 2014

Ivoclar Vivadent, Incorporated
Ms. Donna Marie Hartnett
Director Quality Assurance/Regulatory Affairs
175 Pineview Drive
Amherst, NY 14228

Re: K132984
Trade/Device Name: SR Vivodent S, SR Orthotyp S, SR Ortholingual S
Regulation Number: 21 CFR 872.3590
Regulation Name: Preformed Plastic Denture Tooth
Regulatory Class: II
Product Code: ELM
Dated: October 15, 2013
Received: October 16, 2013

Dear Ms. Hartnett:

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,

for

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

Indications for Use

510(k) Number (if known): K132984

Device Name: SR Vivodent S, SR Orthotyp S, SR Ortholingual S

Indications For Use:

Preformed denture teeth used for total and partial dentures and implant-supported removable prostheses.

Prescription Use X 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
2014.01.14
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