



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

January 24, 2013

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

Re: K123304  
Trade/Device Name: SR NEXCO  
Regulation Number: 21 CFR 872.3690  
Regulation Name: Tooth Shade Resin Material  
Regulatory Class: II  
Product Code: EBF  
Dated: December 26, 2012  
Received: December 27, 2012

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 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" (21 CFR 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

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

K123304

## Indications for Use

510(k) Number (if known): K123304

Device Name: SR NEXCO

Indications For Use:

Intended Use:

SR Nexco is intended to be used as follows:

**Framework-based**

- Veneering of metal-supported restorations
- Veneering of combination dentures (telescope crown veneers)
- Veneering of fixed-removable implant superstructures
- Veneering of gingiva portions in fixed removable implant superstructures
- Veneering of CAD/CAM fabricated metal frameworks
- Masking of model cast frameworks with SR Nexco Opaquer Pink

**Framework-Free**

- Inlays/Onlays/veneers
- Anterior Crowns

**Modification/Characterization**

- Superficial characterization of Ivoclar Vivadent resin teeth with SR Nexco Stains in conjunction with SR Connect and subsequent layering with SR Nexco Paste layering materials
- Shape and shade modifications of Ivoclar Vivadent resin teeth with SR Nexco Paste layering materials in conjunction with SR Connect
- Modification and characterization of Telio CAD and Telio Lab with SR Nexco Stains, Dentin, Incisal and Effect Shades in conjunction with SR Connect.

Prescription Use  AND/OR  
(Part 21 CFR 801 Subpart D)

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

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

Susan Runner DDS, MA

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

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Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

k123304

510(k) Number: \_\_\_\_\_