DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 19 2004

Ms. Donna Marie Hartnett, Esq.
Assistant Corporate Counsel
Ivoclar Vivadent, Incorporated
175 Pineview Drive
Amherst, New York 14228

Re: K040951
Trade/Device Name: SR Adoro®
Regulation Number: 21 CFR 872.3770
Regulation Name: Temporary Crown and Bridge Resin
Regulatory Class: II
Product Codes: EBG and EBF
Dated: April 05, 2004
Received: April 12, 2004

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.

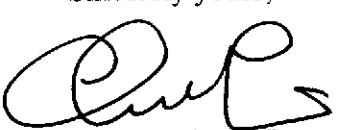
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu S. Lin, PhD
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K040951

Device Name: SR ADORO

Indications For Use:

For Metal Supported restorations with conventional cementation

- Veneering of metal supported restorations using SR Adoro Thermo Guard
- Veneering of combined dentures (e.g. telescope veneers) using SR Adoro Thermo Guard
- Veneering of partially removable implant superstructures using SR Adoro Thermo Guard
- Veneering of gingival parts in partially removable implant superstructures using SR Adoro Thermo Guard
- Fabrication of long-term temporaries using SR Adoro Thermo Guard
- Masking of model cast frameworks with SR Adoro Opaquer Pink.

For Metal-Free restorations

With Adhesive Cementation:

- Inlays/Onlays/Veneers
- Anterior crowns without Vectris framework
- Anterior and posterior crowns with Vectrist framework
- 3-unit anterior and posterior bridges using Vectris framework
- 3-unit inlay-retained bridges with Vectris framework

With Conventional Cementation :

- long-term temporaries with Vectris framework for a maximum duration of wear of 12 months.

For removable prosthetics

- Surface characterization of Ivoclar Vivadent denture teeth with SR Adoro Stains. Surfaces must subsequently be covered with SR Adoro layering material.
- Shade and shape modifications of Ivoclar Vivadent denture teeth with SR Adoro layering material in conjuction with SR Composiv.

Contraindications:

- Veneering of metal support restorations without using SR Adoro Thermo Guard
- 4- and multiple-unit anterior and posterior bridges in conjunction with Vectris
- Posterior crowns without framework support (e.g. alloys, Vectris)
- Cantilever or extension bridges with Vectris
- More than 4 SR Adoro veneers with Vectris framework per quadrant
- Rehabilitation of quadrants without sufficient support by the remaining tooth structure
- Veneering of long span, metal supported bridges (full arch bridges) without sufficient support by the remaining tooth structure
- Veneering of other metal-free frameworks fabricated of materials other than Vectris
- Conventional cementation of fixed metal free restorations
- Long-term metal free temporaries intended for a wear period of longer than 12 months
- Patients with occlusal dysfunctions or parafunctions, such as bruxism, etc.

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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

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

510(k) Number: K040951