SYBRON DENTAL SPECIALTIES

K110747

Section III - 510(k) Summary of Safety and Effectiveness JUN 14 2011

Submitter:

Sybron Dental Specialties, Inc.
1717 W. Collins Avenue
Orange, California 92867
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Wendy Garman - Contact Person

Date Summary Prepared: March 2011

Device Name:

- Trade Name – *TempFlex*
- Common Name – Temporary Dental Restorative Material
- Classification Name – Temporary Crown and Bridge Resin, per 21 CFR § 872.3770

Devices for Which Substantial Equivalence is Claimed:

- Kerr Corporation, *Temphase*

Device Description:

TempFlex is a two component resin based material dispensed and mixed by a cartridge/static mixing tip combination. *TempFlex* is compatible with light cured composites for repair and characterization.

Intended Use of the Device:

TempFlex is indicated for the fabrication of temporary crowns and bridges, inlays, onlays and veneers.

Substantial Equivalence:

TempFlex is substantially equivalent to one other legally marketed device in the United States. *TempFlex* functions in a manner similar to and is intended for the same use as *Temphase* which is currently marketed by Kerr Corporation. *TempFlex* differs from

Temphase in that it utilizes a different initiator system including the addition of a photoinitiator allowing the product to be dual cured and is available in a 4:1 mixing ratio.

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Non-Clinical Test Data

Biocompatibility studies have been completed according to ISO 10993, which demonstrates that *TempFlex* is safe for its intended use.

This 510(k) submission also includes data from bench testing used to evaluate the performance characteristics of *TempFlex* compared to the predicate device, *Temphase*. The characteristics evaluated include Working Time, Setting Time, Compressive Strength, Diametral Strength, Flexural Strength and Shore D Hardness.

Clinical Testing

Clinical testing has not been conducted on this product.

Conclusion:

Based upon the biocompatibility tests and the bench testing, the clinical performance of *TempFlex* is substantially equivalent to 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

Kerr Corporation
C/O Ms. Wendy Garman
Sybron Dental Specialties, Incorporated
1717 West Collins Avenue
Orange, California 92867

JUN 14 2011

Re: K110747
Trade/Device Name: TempFlex
Regulation Number: 21 CFR 872.3770
Regulation Name: Temporary Crown and Bridge Resin
Regulatory Class: II
Product Code: EBG
Dated: May 6, 2011
Received: May 9, 2011

Dear Ms. Garman:

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

Indications for Use

510(k) Number (if known): K110747

Device Name: *TempFlex*

Indications For Use:

TempFlex is indicated for the fabrication of temporary crowns and bridges, inlays, onlays and veneers.

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)

Susan Runner

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

510(k) Number: K110747