

K080311

510(k) SUMMARY

APR 18 2008

DENTSPLY International
Susquehanna Commerce Center West
221 West Philadelphia Street, Suite 60
York, PA 17405-0872

CONTACT: Helen Lewis
DATE PREPARED: February 4, 2008
TRADE OR PROPRIETARY NAME: Modified TempRx Esthetic Provsional System
CLASSIFICATION NAME: Temporary Crown and Bridge Resin, EBG, 872.3770
PREDICATE DEVICES: TempFx Esthetic Provisional System, K061264

DEVICE DESCRIPTION: The Modified TempRx Esthetic Provisional System is a visible light cured composite based resin and accessories used to create provisional restorations for patients waiting for final prosthodontic restorations.

INTENDED USE: The Modified TempRx Esthetic Provisional System is:

- Indicated for the fabrication of all provisional dental restorations for a term of use of up to 6 months.
- Indicated for fabrication of the following long-term provisional dental restorations (without metal substructures) for a term of use greater than 6 months up to 3 years:
 - Inlays/ Onlays
 - Veneers
 - Crowns
 - 3-unit bridges through the 2nd bicuspid.
- Indicated for the build up of a tooth on denture base resins.

TECHNOLOGICAL CHARACTERISTICS: All of the components found in Modified TempRx Esthetic Provisional System have been used in legally marketed devices and/or were found safe for dental use. Modified TempRx Esthetic Provisional System has been evaluated and passed biocompatibility testing for cytotoxicity, mutagenicity, dermal sensitization and irritation.

We believe that the prior use of the components of Modified TempRx Esthetic Provisional System in legally marketed devices, the performance data provided, and the biocompatibility data provided support the safety and effectiveness of the Modified TempRx Esthetic Provisional System for the indicated uses.

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Helen Lewis
Director of Corporate Compliance & Regulatory Affairs
DENTSPLY International
Susquehanna Commerce Center West
221 West Philadelphia Street, Suite 60
York, Pennsylvania 17405-0872

APR 18 2008

Re: K080311
Trade/Device Name: Modified TempRx Esthetic Provisional System
Regulation Number: 21 CFR 872.3770
Regulation Name: Temporary Crown and Bridge Resin
Regulatory Class: II
Product Codes: EBG, EBD
Dated: February 4, 2008
Received: February 6, 2008

Dear Ms. Lewis:

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 (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). 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) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Chiu Lin, Ph.D.

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 STATEMENT

510(k) Number (if known): K080311

Device Name: Modified TempRx Esthetic Provisional System

Indications for Use:

The Modified TempRx Esthetic Provisional System is:

- Indicated for the fabrication of all provisional dental restorations for a term of use of up to 6 months.
- Indicated for fabrication of the following long-term provisional dental restorations (without metal substructures) for a term of use greater than 6 months up to 3 years:
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 - Crowns
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- Indicated for the build up of a tooth on denture base resins.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(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

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