K101493

DENTSPLY

510(k) SUMMARY
for
Advanced Glass Ionomer (K-130) Restorative

DENTSPLY International
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1. Submitter Information:

DENTSPLY International
Susquehanna Commerce Center
221 West Philadelphia Street
York, PA 17405

Contact Person: Helen Lewis
Telephone Number: 717-849-4229
Fax Number: 717-849-4343

AUG 19 2010

Date Prepared: 25 May 2010

2. Device Name:
   - Proprietary Name: Advanced Glass Ionomer (K-130) Restorative
   - Classification Name: Cement, Dental
   - CFR Number: 872.3275
   - Device Class: II
   - Product Code: EMA

3. Predicate Device:
   3M Ketac-Molar Aplicap (K960954)

4. Description of Device:

Advanced Glass Ionomer (K-130) is a fast-setting, high viscosity radiopaque chemical curing glass ionomer restorative material. The restorative is available in 5 shades and comes in mixing capsules for direct application.

5. Indications for Use:

Especially designed for:
- Semi-permanent restorations of Class I and II cavities in posterior teeth.

In addition suitable for:
- Restoration of deciduous teeth.
- Restoration of Class V lesions and cavities.
- Restoration of Class III cavities.
- Base/ Core-build-up. When used as a core-build-up, 2/3 of the remaining coronal dentine or at least 2mm of circumferential coronal dentine should be left for retention.

6. Description of Safety and Substantial Equivalence:

Technological Characteristics.

The technological characteristics (i.e., chemical composition and device function) of Advanced Glass Ionomer (K-130) Restorative are similar to that of the predicate device.

Non-Clinical Performance Data.

A cytotoxicity test was performed for the Advanced Glass Ionomer (K-130) Restorative material as well as chemical analyses of leachable organic and inorganic compounds. The Advanced Glass Ionomer (K-130) Restorative material has been demonstrated as biocompatible and safe for its intended use.

In-vitro bench tests were performed on the Advanced Glass Ionomer (K-130) Restorative material. The results indicated that the Advanced Glass Ionomer (K-130) Restorative material meets or exceeds the requirements of ISO-9917:2007 (*Dentistry: Water based cement, Part I, Powder/Liquid acid-base cements*) and safe for its intended use.

Conclusion as to Substantial Equivalence

We believe that the prior use of the glass ionomer restorative material in legally marketed devices and the performance and biocompatibility data provided support the safety and effectiveness of Advanced Glass Ionomer (K-130) Restorative material for the indicated uses.

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

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

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Re: K101493
Trade/Device Name: Advanced Glass Ionomer (K-130) Restorative
Regulation Number: 21 CFR 872.3275(b)
Regulation Name: Dental Cement
Regulatory Class: II
Product Codes: EMA, EBF, EBC, and EJK
Dated: May 28, 2010
Received: June 1, 2010

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. 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

SECTION 4: INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K101493

Device Name: Advanced Glass Ionomer (K-130) Restorative

Indications for Use:

Advanced Glass Ionomer (K-130) Restorative Material is indicated for semi-permanent restorations of class I and II cavities in posterior teeth; Restoration of deciduous teeth; Restoration of Class V lesions and cavities; Restoration of Class III cavities; Base/ Core-build-up. When used as a core-build-up, 2/3 of the remaining coronal dentine or at least 2mm of circumferential coronal dentine should be left for retention.

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)

Ram Mulay for MSR

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

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