December 28, 2011

Contact:
Kenneth J. Berk
80 Oakland Street
PO Box 780
Watertown, MA 02472 USA

DEVICE:

Trade Name: NuCal
Classification Name: Calcium hydroxide cavity liner.
FDA Product Code: 76 EJK, 21 CFR Part 872.3250

PREDICATE DEVICES:

Pulpdent TempCanal
Pulpdent Multi-Cal
UltraDent UltraCal XS

INTENDED USE: NuCal is used by the dental professional as a cavity liner and as a temporary root canal dressing.

DESCRIPTION: NuCal is a non-setting, pre-mixed, radiopaque calcium hydroxide paste that has a pH > 12, is easily removed from the root canal with water, has been designed for ease of handling and will flow through a 27 gauge applicator tip.

COMPARISON WITH PREDICATE PRODUCTS:

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>DESCRIPTION</th>
<th>INTENDED USE</th>
<th>COMPOSITION</th>
</tr>
</thead>
<tbody>
<tr>
<td>NuCal</td>
<td>Non-setting, pre-mixed, radiopaque calcium hydroxide paste</td>
<td>Cavity liner and temporary root canal dressing.</td>
<td>Calcium hydroxide, Barium sulfate, Polyethylene glycol, Water</td>
</tr>
<tr>
<td>Pulpdent TempCanal K944945</td>
<td>Non-setting, pre-mixed, radiopaque calcium hydroxide paste</td>
<td>Cavity liner and temporary root canal dressing.</td>
<td>Calcium hydroxide, Barium sulfate, Aqueous gel matrix</td>
</tr>
<tr>
<td>Pulpdent Multi-Cal K944945</td>
<td>Non-setting, pre-mixed, radiopaque calcium hydroxide paste</td>
<td>Cavity liner and temporary root canal dressing.</td>
<td>Calcium hydroxide, Barium sulfate, Aqueous gel matrix</td>
</tr>
<tr>
<td>UltraDent UltraCal XS K970114</td>
<td>Non-setting, pre-mixed, radiopaque calcium hydroxide paste</td>
<td>Cavity liner and temporary root canal dressing.</td>
<td>Calcium hydroxide, Barium sulfate, Aqueous matrix</td>
</tr>
</tbody>
</table>
SUMMARY OF PERFORMANCE TESTING – BENCH

The following test results demonstrate that NuCal performs as intended:

- **Appearance**: Thin white paste.
- **Consistency**: Smooth, homogenous, thin paste.
- **Paste characteristic**: Dispenses easily through 27 gauge applicator tip without clogging or force.
- **Specific gravity**: 1.470 g/ml
- **pH**: > 12
- **Radiopacity**: Equal to the same thickness of aluminum
- **Shelf life**: Two years, based on accelerated testing at 37°C

CONCLUSION:

From the above comparisons, the bench testing and the decades of organizational experience with calcium hydroxide preparations, it can be concluded that NuCal is substantially equivalent in design, composition, performance and intended use to the predicate products listed above. The predicate products have been found substantially equivalent under the 510(k) Premarket Notification process as Class II Dental Devices under CFR 872.3250 and have been used by dental professionals for more than 20 years. A search of the relevant scientific literature shows that calcium hydroxide pastes used for cavity lining and root canal dressing have been studied since the 1950’s. See References below.

REFERENCES


10. Kundsin RB, Perkins RE. Test of antibacterial activity of Pulpdent TempCanal (Calcium hydroxide preparation). Kundsin Laboratory, Harvard Medical School, Brigham and Women’s Hospital.


Mr. Kenneth J. Berk  
Director  
Pulpdent Corporation  
80 Oakland Street  
Watertown, Massachusetts 02472

Re: K120003  
  Trade/Device Name: Nucal  
  Regulation Number: 21 CFR 872.3250  
  Regulation Name: Calcium Hydroxide Cavity Liner  
  Regulatory Class: II  
  Product Code: EJK  
  Dated: February 17, 2012  
  Received: February 21, 2012

Dear Mr. Berk:

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/CDRHOffice s/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,

[Signature]

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: K120003

Device Name: Pulpdent NuCal

Indications For Use:

NuCal is a non-setting, pre-mixed, radiopaque calcium hydroxide paste used as a cavity liner and as a temporary root canal dressing.

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)

[Signature]

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

510(k) Number: K120003