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8. 510(k) Summary

This 510(k) summary is in accordance with the requirements of 21 CFR 807.92(c).

Submission Date: November 23, 2010

510 (k) Notification: Traditional 510(k) Submission

Submitter Information:

Company: Colgate-Palmolive Company
Address: 909 River Road
Piscataway, NJ 08855 USA
Contact: Charles P. Ireland, MBA
Director of Regulatory Affairs, North America
Telephone: (732) 878-7519
Telefax: (732) 878-7135
Email:

Device Information:

Establishment Registration number:	2418748
Common Device:	Dentifrice, Toothpaste
Trade Name:	Colgate® Desensitizing Dental Cream
Classification Name:	Varnish, Cavity; 21 CFR § 872.3260
Classification Product Code:	LBH
Classification Panel:	Dental
Class:	II

Intended Use:
For the management of sensitive teeth.
Provides rapid relief from painful sensitivity of teeth to cold, heat, acids, sweets, or contact.
Rapid Desensitizer

Reason for the 510(k): This premarket notification (510(k)) submission is intended to modify the marketing status of our legally marketed device, Rx home-use DenClude (originally called ProClude-Sensitive) Desensitizing Cream (K003482) from Prescription use to Over-the-counter use. All of the components for Colgate® Desensitizing Dental Cream (CDDC) are similar to the previously cleared DenClude Desensitizing Cream. These intended use are consistent with the indications cleared in the DenClude 510(k).

Predicate Devices used to claim substantial equivalence to:
Colgate® Desensitizing Dental Cream has the same intended use and utilizes the same technological characteristics as these legally marketed predicate devices. The components of CDDC have previously been cleared by CDRH in dental devices, including Colgate-

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Palmolive's ProClude® (K002989) and DenClude® (K003482) and the other predicate devices.

1. Trade Name: DenClude® Desensitizing Dental Cream
   Owner: Colgate-Palmolive Company
   Original name: ProClude-Sensitive
   510(k) number: K003482
   Product Code: LBH

2. Trade Name: ProClude® Prophylaxis Paste
   Owner: Colgate-Palmolive Company
   510(k) number: K002989
   Product Code: EJR

3. Trade Name: Oravive™ Tooth Revitalizing Paste
   Applicant: NovaMin Technology, Inc
   510(k) number: K040473
   Product Code: LBH

4. Trade Name: Protect™ Tooth Desensitizer
   Applicant: Sunstar Butler
   510(k) number: K050486
   Product Code: LBH

Technological Characteristics
The general components, intended use and application of CDDC are substantially equivalent to those of the legally marketed predicate devices. Open dentin tubules allow the fluid within to transmit external stimuli to the nerves within the dentin pulp and to trigger a pain response, resulting in dentin hypersensitivity. The components of CDDC physically adhere to exposed dentin forming a solid plug, stopping fluid movement. This physical mechanism of action is responsible for the product's ability to achieve its intended purpose.

Performance Data
In vitro studies show that CDDC demonstrates physical occlusion of the dentin tubules, creating a protective barrier that prevents external stimuli from reaching the nerves that reside in the dentin pulp. Clinical studies show that instant sensitivity relief occurs with direct application..

The conclusions drawn from the performance testing are that the device is safe and as effective as the predicate devices. Furthermore, the device performs its intended use as well as or better than the legally marketed predicate devices and complies with several ISO standards.

Performance Standards

CDDC complies with the following ISO standards:

- ISO 11609, Dentistry - Toothpastes - Requirements, test methods and marking, 1998.
- ISO 10993-1:2003(E), Biological evaluation of medical devices -- Part 1: Evaluation and testing.
- ISO 7405: 2008 (E), Dentistry - Evaluation of biocompatibility of medical devices used in dentistry.

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

Mr. Charles P. Ireland
Director of Regulatory Affairs, North America
Colgate-Palmolive Company
909 River Road
Piscataway, New Jersey 08855

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Re: K103461
Trade/Device Name: Colgate® Desensitizing Dental Cream
Regulation Number: 21 CFR 872.3260
Regulation Name: Cavity Varnish
Regulatory Class: II
Product Code: LBH
Dated: September 8, 2011
Received: September 9, 2011

Dear Mr. Ireland:

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

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7. Indications for Use

510(k) Number (if known): K103461

Device Name: Colgate® Desensitizing Dental Cream

Indications for Use:

For the management of sensitive teeth.
Provides rapid relief from painful sensitivity of teeth to cold, heat, acids, sweets, or contact.
Rapid Desensitizer

Prescription Use _____	AND/OR	Over-The-Counter Use ___X___
(Part 21 CFR 801 Subpart D)		(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF 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: K103461