

K121698

**SECTION 5:  
510(k) SUMMARY  
for**

AUG 6 2012

**NUPRO® Sensodyne® Prophylaxis Paste with NovaMin®**

**1.0 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

Date Prepared: August 2, 2012

**2.0 Device Name**

Proprietary Name: NUPRO® Sensodyne® Prophylaxis Paste with NovaMin®  
Common Name: Prophy Paste  
Classification Name: Oral abrasive polishing agent  
CFR Number: 872.6030  
Device Class: I  
Product Code: EJR

**3.0 Predicate Device**

Butler Prophylaxis Paste with NovaMin, product code EJR, K024343  
Indications for Use – Butler Prophylaxis Paste with NovaMin® is intended for cleaning and polishing procedures as part of a professionally administered dental prophylaxis treatment. Secondly, Butler Prophylaxis Paste with NovaMin® can be used for the immediate relief of tooth sensitivity, post-scaling and root planing.

**4.0 Description of Device**

NUPRO® Sensodyne® is a premium prophylaxis paste containing NovaMin®, a calcium sodium phosphosilicate. The dye-free formulations are available in fluoride and non-fluoride formulations, with two different grits to gently remove dental plaque and stains. The Polish Grit is ideal for prophy procedures requiring minimal tooth abrasion. The Stain Removal Grit is suitable for most cleaning procedures where a high level of polish is desired for stain removal.

## 5.0 Indications for Use

NUPRO® Sensodyne® Prophylaxis Paste with NovaMin® is intended for cleaning and polishing procedures, including prior to and after scaling and root planing as part of a professionally administered dental prophylaxis treatment. Secondly, NUPRO® Sensodyne® Prophylaxis Paste with NovaMin® can be used for the immediate relief of tooth sensitivity and for lasting sensitivity relief for up to 4 weeks (28 days) after just one application.

## 6.0 Identification of Risk Analysis Method

Risk analysis was performed on NUPRO® Sensodyne® Prophylaxis Paste with NovaMin® utilizing a process based on ISO 14971:2009. The results of the risk analysis performed on NUPRO® Sensodyne® Prophylaxis Paste with NovaMin® concluded that the device has acceptable low risks, and any risks that are applicable to the device are mitigated by design and process controls that have already been implemented.

## 7.0 Description of Safety and Substantial Equivalence

### 7.1 Technological Characteristics

The technological characteristics of the NUPRO® Sensodyne® Prophylaxis Paste with NovaMin® are very similar to the Butler Gum® Prophylaxis Paste with NovaMin®. Both pastes include pumice to clean and polish teeth and NovaMin® for sensitivity relief. The formulation differs slightly as the vehicles for active ingredients (pumice and NovaMin®) are composed of slightly different materials, but both vehicles perform the same function and are considered safe and effective.

### 7.2 Non-Clinical Performance Data

Non-clinical performance data includes testing to determine the cleaning ability of the NUPRO® Sensodyne® Prophylaxis Paste with NovaMin® to remove stain and stability testing. Biocompatibility has been substantiated by human clinical studies. The data analyzed in the various tests substantiate that NUPRO® Sensodyne® Prophylaxis Paste with NovaMin® is as safe and effective as the Butler Gum® Prophylaxis Paste with NovaMin®.

### 7.3 Clinical Performance Data

A single site, double-blind, randomized, three arm parallel group study to determine the efficacy of NUPRO® Sensodyne® Propphy Paste with NovaMin® in reducing tooth hypersensitivity immediately after a single application following dental scaling and root planing, as well as longer lasting relief after the dental procedure was performed on human subjects. 151 participants were evaluated that were 18 years of age or older. The participants had at least two teeth that satisfied the qualifying response to stimuli for both parameters assessed (tactile and air blast). Evaluations occurred at baseline (treatment visit) and at a 28-day recall.

During the entire trial period, there were no cases of relevant pathological conditions observed by the examiner associated with test product usage. No serious or non-serious adverse events occurred during the course of the study.

The results of the study concluded that NUPRO® Sensodyne® Prophy Paste with NovaMin® showed statistically significant reductions in hypersensitivity immediately after dental scaling and root planing and for 4 weeks (28 days) after just one application. The results of the clinical study therefore support the expansion of the indications for use of the subject NUPRO® Sensodyne® Prophy Paste with NovaMin®. Since there were no adverse events observed NUPRO® Sensodyne® Prophy Paste with NovaMin® is deemed substantially equivalent to the predicate Butler Gum® Prophylaxis Paste with NovaMin®.

#### 7.4 Conclusion as to Substantial Equivalence

The NUPRO® Sensodyne® Prophylaxis Paste with NovaMin® has been tested through *in vitro* testing for its ability to clean and remove stain from teeth, for abrasiveness, and stability. In addition, clinical evidence is presented which supports the sensitivity reduction effectiveness and safety of the subject device thereby supporting the additional indications for use. The modified NUPRO® Sensodyne® Prophylaxis Paste with NovaMin® is therefore substantially equivalent to the predicate Butler Gum® Prophylaxis Paste with NovaMin®.



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 Regulatory Affairs  
DENTSPLY International Incorporated  
Susquehanna Commerce Center  
221 West Philadelphia Street, Suite 60W  
York, Pennsylvania 17405-0872

AUG 6 2012

Re: K121698

Trade/Device Name: NUPRO<sup>®</sup> Sensodyne<sup>®</sup> Prophylaxis Paste with NovaMin<sup>®</sup>  
Regulation Number: 21 CFR 872.6030  
Regulation Name: Oral Cavity Abrasive Polishing Agent  
Regulatory Class: I  
Product Code: EJR  
Dated: June 7, 2012  
Received: June 8, 2012

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,



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): K121698

Device Name: NUPRO® Sensodyne® Prophylaxis Paste with NovaMin®

Indications for Use:

NUPRO® Sensodyne® Prophylaxis Paste with NovaMin® is intended for cleaning and polishing procedures, including prior to and after scaling and root planing as part of a professionally administered dental prophylaxis treatment. Secondly, NUPRO® Sensodyne® Prophylaxis Paste with NovaMin® can be used for the immediate relief of tooth sensitivity and for lasting sensitivity relief for up to 4 weeks (28 days) after just one application.

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)

*Sheena Green for*  
*Dr. Susan Runner*  
Sheena Green  
(Division Sign-Off)

Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

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