K041371

AUG 2 3 2004

SECTION E
510(k) SUMMARY

1. SUBMITTER INFORMATION:

Name:	NovaMin Technology, Inc.
Address:	13709 Progress Blvd., #23 Alachua, Florida 32615 USA
Phone:	(386) 418-1551
Facsimile:	(386) 418-1465
Contact:	David C. Greenspan, Ph.D.

Preparation Date: May 19, 2004

2. DEVICE NOMENCLATURE:

Trade Name:	Butler NuCare™ Prophylaxis Paste with NovaMin®
Common Name:	Dental Prophylaxis Paste
Classification Name:	Prophylaxis Paste

3. LEGALLY MARKETED PREDICATE DEVICE:

Device Name:	Butler GUM® Prophylaxis Paste with NovaMin®
510(k) Number:	K024343
Applicant:	NovaMin Technology, Inc.

4. DEVICE DESCRIPTION:

Butler NuCare™ Prophylaxis Paste with NovaMin® is a product that is intended for cleaning and polishing procedures as a part of a professionally administered dental prophylaxis treatment. Butler NuCare™ Prophylaxis Paste with NovaMin® is also designed to physically occlude dentinal tubules for the immediate relief of tooth sensitivity, post-scaling and root planing. NovaMin® (calcium sodium phosphosilicate) is composed of elements that occur naturally in the body (Ca, Na, Si, P, and O). When exposed to an aqueous environment, NovaMin® undergoes a rapid surface reaction, allowing it to physically occlude tubules. Within a short period of time, essentially all of the NovaMin® reacts to form hydroxycarbonate apatite (HCA), which is chemically and structurally similar to natural tooth mineral.

5. INTENDED USE:

Butler NuCare® Prophylaxis Paste with NovaMin® is intended for cleaning and polishing procedures as a part of a professionally administered dental prophylaxis treatment. Secondarily, Butler NuCare™ Prophylaxis Paste with NovaMin® can be used for the immediate relief of tooth sensitivity, post-scaling and root planing.

6. TECHNOLOGICAL CHARACTERISTICS:

The technological characteristics of Butler NuCare™ Prophylaxis Paste with NovaMin® and Butler GUM® Prophylaxis Paste with NovaMin® are the same. Both devices are designed to polish and clean the tooth surface as part of a professionally administered dental prophylaxis treatment. Both devices are also designed to relieve tooth hypersensitivity associated with exposed dentin by the deposition of a calcium phosphate layer onto the tooth surface. Both devices use NovaMin® to produce a calcium phosphate layer that occludes dentinal tubules and blocks hydrodynamic flow. The two devices are somewhat different in the ingredients used to make the base of the products, and .in the material used as the abrasive agent.

7. SAFETY AND PERFORMANCE DATA:

Many different biocompatibility tests have been performed on the NovaMin® particulate, the active ingredient in Butler NuCare™ Prophylaxis Paste with NovaMin®. The results of these tests indicate there is no evidence of any hazardous effects to the patient if the product is used as directed.

The tubule occlusion efficacy of Butler NuCare™ Prophylaxis Paste with NovaMin® was evaluated using an *in vitro* dentin block model. The results indicate Butler NuCare™ Prophylaxis Paste with NovaMin® occludes a significant number of tubules when compared with controls.

8. CONCLUSIONS:

Butler NuCare™ Prophylaxis Paste with NovaMin® is considered to be substantially equivalent to the legally marketed predicate device, Butler GUM® Prophylaxis Paste with NovaMin® (K024343). The provided dentinal tubule occlusion data and biocompatibility data demonstrate the safety and efficacy of Butler NuCare™ Prophylaxis Paste with NovaMin® for the intended uses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 3 2004

Dr. David C. Greenspan
Vice President & Chief Technology Officer
NovaMin Technology, Incorporated
13709 Progress Boulevard #23
Alachua, Florida 32615

Re: K041371
Trade/Device Name: Butler NuCare™ Prophylaxis Paste with NovaMin®
Regulation Number: 872.6030
Regulation Name: Oral Cavity Abrasive Polishing Agent
Regulatory Class: 1
Product Code: EJR
Dated: May 21, 2004
Received: May 25, 2004

Dear Dr. Greenspan:

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 (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/dsma/dsmamain.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

SECTION D
STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K041371

Device Name: Butler NuCare™ Prophylaxis Paste with NovaMin®

INDICATIONS FOR USE:

Butler NuCare™ Prophylaxis Paste with NovaMin® is intended for cleaning and polishing procedures as part of a professionally administered dental prophylaxis treatment. Secondarily, Butler NuCare™ Prophylaxis Paste with NovaMin® can be used for the immediate relief of sensitivity, post-scaling and root planing.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF 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 K041371

Prescription Use __X__ OR (Per 21 CFR 801.109) Over-The-Counter Use ____