K080228

# SECTION E
# 510(k) SUMMARY

MAR 27 2008

## 1. SUBMITTER INFORMATION:


| | |
|---|---|
| Name: | NovaMin Technology, Inc. |
| Address: | 13859 Progress Blvd., #600<br>Alachua, Florida 32615 USA |
| Phone: | (386) 418-1551 |
| Facsimile: | (386) 418-1465 |
| Contact: | Robert G. Rothfritz |


| | |
|---|---|
| Preparation Date: | January 9, 2008 |

## 2. DEVICE NOMENCLATURE:

| | |
|---|---|
| Trade Name: | Oralief™ OTC Toothpaste for Sensitive Teeth |
| Common Name: | Dentifrice, Toothpaste |
| Classification Name: | Cavity Varnish (21 CFR 872.3260 Product Code LBH) |

## 3. LEGALLY MARKETED PREDICATE DEVICE:

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|---|---|
| Device Name: | Oralief™ Therapy for Sensitive Teeth |
| 510(k) Number: | K040858 |
| Applicant: | NovaMin Technology, Inc. |

## 4. DEVICE DESCRIPTION:

Oralief™ OTC Toothpaste for Sensitive Teeth is a daily-use, fluoride-free toothpaste device that incorporates NovaMin® (calcium sodium phosphosilicate) as its active ingredient. The non-aqueous formulation is designed to clean teeth as well as to physically occlude dentin tubules for the reduction of tooth sensitivity. 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:

Oralief™ OTC Toothpaste for Sensitive Teeth is a fluoride-free daily use cleaning toothpaste that also provides rapid and continual relief from tooth sensitivity due to cold, heat, acids, sweets or contact, through its action of the occlusion of dentin tubules.

## 6. TECHNOLOGICAL CHARACTERISTICS:

The technological characteristics of Oralief™ OTC Toothpaste for Sensitive Teeth are identical to the predicate device Oralief™ Therapy for Sensitive Teeth. Oralief™ OTC Toothpaste for Sensitive Teeth is designed to relieve hypersensitivity associated with exposed dentin by the deposition of a calcium phosphate layer onto the tooth surface that occludes dentinal tubules and blocks hydrodynamic flow.

## 7. SAFETY AND PERFORMANCE DATA:

Many different biocompatibility tests have been performed on NovaMin. The results of these tests indicate that there is no evidence of any hazardous effects to the patient if the product is used as directed.

The tubule occlusion efficacy of Oralief™ OTC Toothpaste for Sensitive Teeth was evaluated using an *in vitro* dentin block model. The results indicate that Oralief™ OTC Toothpaste for Sensitive Teeth occludes a statistically significant number of tubules when compared to controls.

The relative abrasion level of Oralief™ OTC Toothpaste for Sensitive Teeth was evaluated at Indiana University School of Dentistry. The procedure used was the ADA recommended procedure for determination of toothpaste abrasivity. The result was a mean Radioactive Dentin Abrasion (RDA) value of 125.55. This RDA value is well under the limit considered safe for daily-use (RDA value < 250).

## 8. CONCLUSIONS:

Oralief™ OTC Toothpaste for Sensitive Teeth is considered to be substantially equivalent to the legally marketed predicate device, Oralief™ Therapy for Sensitive Teeth (K040858) because the compositions and actions are identical. The provided tubule occlusion studies, dentin abrasion study, and biocompatibility data demonstrate the safety and efficacy of Oralief™ OTC Toothpaste for Sensitive Teeth as a daily use toothpaste.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 7 2008

Mr. Robert G. Rothfritz
Vice President, Operations
NovaMin Technology, Incorporated
13859 Progress Boulevard, #600
Alachua, Florida 32615

Re: K080228
Trade/Device Name: Oralief™ OTC Toothpaste for Sensitive Teeth
Regulation Number: 21 CFR 872.3260
Regulation Name: Cavity Varnish
Regulatory Class: II
Product Code: LBH
Dated: January 28, 2008
Received: January 30, 2008

Dear Mr. Rothfritz:

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 (240) 276-0115. 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/industry/support/index.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

Enclosure

## SECTION D
## STATEMENT OF INDICATIONS FOR USE

**510(k) Number (if known):** K080228

**Device Name:** Oralief™ OTC Toothpaste for Sensitive Teeth

**INDICATIONS FOR USE:**

Oralief™ OTC Toothpaste for Sensitive Teeth is a fluoride-free daily use cleaning toothpaste that provides rapid and continual relief from tooth sensitivity due to cold, heat, acids, sweets or contact, through its action of the occlusion of dentin tubules

Prescription Use _____ OR (Per 21 CFR 801.109) Over-The-Counter Use X

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kai Hanley for MSR

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

510(k) Number: K080228