DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

Cosmedent, Inc
Hiren Patel
Director Of Regulatory Affairs
401 N Michigan Ave, Suite 2500
Chicago, Illinois 60611

February 24, 2017

Re: K163480
Trade/Device Name: Renamel Nano +plus
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF
Dated: November 29, 2016
Received: December 12, 2016

Dear Hiren Patel:

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 contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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,

Susan Runner DDS, MA

For Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*

Device Name
Renamel® NANO™ +plus

Indications for Use *(Describe)*

Renamel® NANO™ +plus is designed for,

- Class I-V dental restorations
- Direct veneering of anterior teeth
- Splinting
- Repair of composite or ceramic restorations

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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# Section 5: 510(k) Summary

**Date Prepared:** 12/21/2016

**Company Name:** Cosmedent, Inc
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**Contact Person:** Hiren Patel
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**Trade name:** Renamel® NANO™ +plus (NANO COMPOSITE)

**Common Name:** Nano-Hybrid Dental Composite

**Regulatory Class:** Class II

**Device Panel:** Dental Panel

**Regulation Number:** 21 CFR 872.3690

**Classification Name:** Tooth Shade Resin Material

**Product Code:** EBF

**Substantially Equivalent to:**
The Renamel® NANO™ +plus is substantially equivalent to the Renamel® NANO™ (Cosmedent, Inc. K070583) cleared by FDA on April 16 2007.

**Device Description:**
Renamel® NANO™ +plus is a light-cure composite resin fabricated from multifunctional acrylic monomers and silicaceous fillers. These materials possess physical and mechanical properties that allow them to function in the oral cavity with esthetic qualities that mimic natural tooth appearance.

**Intended Use/Indication for Use:**
Renamel® NANO™ +plus is designed for,

- Class I-V dental restorations
- Direct veneering of anterior teeth
- Splinting
- Repair of composite or ceramic restorations

**Substantial Equivalence Summary**
The mechanical properties, the intended use and the indication for use of Renamel® NANO™ +plus and its predicate: Renamel® NANO™ are the same. The compressive strength, flexural strength, depth of cure, particle size range and radiopacity of both composite materials fall within

very similar values. The difference between Renamel® NANO™ and Renamel® NANO™ +plus can be found in chemical (formulation) and handling properties. These properties have a slight impact on the mechanical and physical properties of the composite material.

**Table 5.1:** Comparison of Renamel® NANO™ +plus / Renamel® NANO™ (K070583)

| Property / Standard | Specification | Renamel®NANO™+plus | Renamel®Nano™ (K070583) |
|---|---|---|---|
| Application properties/ delivery form | --- | Preloaded, plastic-screw fed syringe (5 grams), and individual unit dose compules (0.25 gram). The material is extruded directly (without tip) onto a suitable pad and placed in the prepared cavity and light cured. | |
| Light curing wavelength | --- | LED and Halogen light at wavelength range of 400 – 500 nm. | |
| Depth of cure (other than opaque materials) ISO 4049:2009; Type1, Class2, Group1 | ≥ 1.5mm | 2.0 mm ± 0.2mm | 2.0 mm ± 0.2mm |
| Flexural strength ISO 4049:2009; Type1, Class2, Group1 | ≥ 80 MPa | 127 MPa ± 12 MPa | 125 MPa ± 12 MPa |
| Water sorption ISO 4049:2009; Type1, Class2, Group1 | ≤ 40 µg/mm³ | 13.5 µg/mm³ ± 0.1 µg/mm³ | 21.2 µg/mm³ ± 0.1 µg/mm³ |
| Solubility ISO 4049:2009; Type1, Class2, Group1 | ≤ 7.5 µg/mm³ | 0.0 µg/mm³ ± 0.05 µg/mm³ | 0.13 µg/mm³ ± 0.05 µg/mm³ |
| Radiopacity ISO 4049:2009; Type1, Class2, Group1 | ≥ 1mm | 2.4 mm ± 0.2mm | 2.7 mm ± 0.2mm |
| Compressive strength | ≥ 300 MPa | 360 MPa ± 36 MPa | 367 MPa ± 36 MPa |
| Modulus of elasticity | ≥ 7000 Mpa | 10475 MPa ± 1000 MPa | 8925 MPa ± 900 MPa |

**Substantial equivalent in Safety and efficacy (Biocompatibility)**

The data analyzed from the toxicological evaluation of the new added components, and the results of the biocompatibility tests (10993-xx) substantiate that the Renamel® NANO™ +plus is safe and effective as the predicate Renamel® NANO™ (K070583).

**Results/summary of the Substantial Equivalence**

The subject device Renamel® NANO™ +plus has been compared with its predicate Renamel® NANO™ with regard to indication (intended use), performance data and chemical composition. In order to obtain better handling properties (stiffness and sculptability), the composition of the device has been modified. None of the new ingredients in the subject device poses any new concerns of safety and effectiveness, and comparison shows, that Renamel®NANO™+plus is substantially equivalent to the predicate Renamel®NANO™ (K070583).