Cosmedent, Inc
Mary Nowak
Vice President Development & Regulatory Affairs
401 N. Michigan Ave, Suite 2500
Chicago, Illinois 60611

December 5, 2017

Re: K172707
Trade/Device Name: Renamel® Microfill
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF
Dated: September 5, 2017
Received: September 8, 2017

Dear Mary Nowak:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mary S. Runner -S

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)*
K172707

Device Name
Renamel® Microfill

Indications for Use *(Describe)*

Renamel® Microfill is designed for,

- Direct anterior veneers
- Anterior Class III and IV restorations
- Class V restorations (cervical caries, root erosion, wedge-shaped defects)
- Closing of diastemas
- Repair of composite and ceramic veneers
- Top layer of Class I and II 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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Section 5: 510(k) Summary

K172707

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

Date Prepared: 12/01/2017

501(k) Submitter:
Cosmedent, Inc.
401 N Michigan Ave,
Suite 2500,
Chicago, IL, 60611
Tel: 312-644-9586, Fax: 312-644-9752

Contact Person:
Gary Chuven
Director of Regulatory Affairs
Cosmedent, Inc.
Tel: 312-644-9395 ext. 117
Email: gary@cosmedent.com

Trade Name: Renamel® Microfill (Composite)

Common Name: Light-Cured Dental Restorative Composite

Regulatory Class: Class II

Device Panel: Dental Panel

Regulation Number: 21 CFR 872.3690

Classification Name: Tooth Shade Resin Material

Product Code: EBF

Predicate Device: Renamel® Esthetic Restorative System (K854755, Cosmedent, Inc.) Cleared on March 13, 1986

Description of Device:

Renamel® Microfill is light-cured, microfilled, highly polishable dental restorative material. According to the applicable FDA recognized consensus standard ISO 4049 - "Dentistry – Polymer-based restorative materials", this device is classified as Type 1, Class 2, Group 1: Polymer-based restorative materials, involving occlusal surfaces, which uses external energy source for intra-orally curing. Renamel® Microfill consists of multi-functional acrylic Resin and fillers of 0.04 – 0.2 micron sized particles of inorganic and prepolymerized composite (70% by weight, 60% by volume). These devices possess physical and mechanical properties that allow them to function in the oral cavity with esthetic quality that mimics natural enamel surface.

Intended Use:

Renamel® Microfill is intended to be used to create lifelike dental restoration.

Indications for Use:

Renamel® Microfill is designed for,

- Direct anterior veneers
- Top layer of Class I and II restorations

- Anterior Class III and IV restorations
- Class V restorations (cervical caries, root erosion, wedge-shaped defects)
- Closing of diastemas
- Repair of composite and ceramic veneers

Substantial Equivalence Discussion:

Intended Use/ Indication for Use

Subject Renamel® Microfill lists the specific indication for use to provide better understanding to the healthcare professional. The original statement in PMN K854755 was considered insufficiently specific. Specifying the indications for use does not add any new safety and effectiveness concerns. Also, it does not change the intended use, "to create lifelike dental restorations."

Chemical Composition

Chemical composition of the subject Renamel® Microfill and predicate Renamel® Composite Resin is somewhat different. The changes in the chemical composition are to comply with the requirements of the ISO 4049 Type 1 Class 2 Group 1 standards with similar handling and polishing properties. The predicate device does not achieve the necessary flexural strength values for Type 1 restorative materials. In addition, subject Renamel® Microfill has more shades for dental restoration and a new single use package (Compule). Neither the changes in the chemical composition nor the new single use package of the subjected Renamel® Microfill add any new concerns of safety.

The table below depicts the modification associated with Renamel® Microfill and Renamel® Composite Resin (K854755).

Table 5.1: Predicate Renamel® Resin Composite and Proposed Renamel® Microfill

Property / Standard	Specification	Renamel® Microfill	Renamel® Composite Resin (K854755)
Application properties/ delivery form	---	Preloaded, plastic-screw fed syringe (4 grams), and individual unit dose compules (0.20 gram). The material is extruded directly (without tip) onto a suitable pad and placed in the prepared cavity and light cured.	Preloaded, plastic-screw fed syringe (2.5 grams). The material is extruded directly (without tip) onto a suitable pad and placed in the prepared cavity and light cured.
Intended use	---	Intended to be used to create lifelike dental restoration.	Intended to be used to create lifelike dental restoration.
Indication for Use	---	Renamel® Microfill is designed for, • Direct anterior veneers • Top layer of Class I and II restorations • Anterior Class III and IV restorations • Class V restorations (cervical caries, root erosion, wedge-	----

Property / Standard	Specification	Renamel® Microfill	Renamel® Composite Resin (K854755)
		shaped defects) • Closing of diastemas • Repair of composite and ceramic veneers	
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	2.15 mm ± 0.1mm	2.0 mm ± 0.1mm
Flexural strength ISO 4049:2009; Type1, Class2, Group1	≥ 80 MPa	95.5 MPa ± 3 MPa	76 MPa ± 4 MPa
Water sorption ISO 4049:2009; Type1, Class2, Group1	≤ 40 μg/mm³	15 μg/mm³ ± 0.5 μg/mm³	12.5 μg/mm³ ± 0.5 μg/mm³
Solubility ISO 4049:2009; Type1, Class2, Group1	≤ 7.5 μg/mm³	0.9 μg/mm³	1.1 μg/mm³
Radiopacity ISO 4049:2009; Type1, Class2, Group1	≥ 1mm	None (not claimed)	None (not claimed)
Compressive strength	≥ 320 MPa	410 MPa ± 40 MPa	390 MPa ± 30 MPa
Modulus of elasticity	≥ 3000 MPa	5100 MPa ± 300 MPa	4575 MPa ± 440 MPa

Substantial equivalent in Safety (Biocompatibility)

Biocompatibility studies were performed on the subject Renamel® Microfill. The data were analyzed and the results of the biocompatibility tests (ISO10993-1, ISO10993-2, ISO10993-5, ISO10993-10, & ISO10993-11) substantiate that Renamel® Microfill with its modification in composition is as safe (biocompatible) as the predicate Renamel® Composite Resin.

Conclusion:

The subject device Renamel® Microfill has been compared with its predicate Renamel® Composite Resin with regards to intended use, performance data and chemical composition. In order to provide compliance with ISO 4049 Type 1 Class 2 (Class I&II restorations), the composition of the device has been modified. None of the new ingredients (pigments, polyacrylic resin) in the subject device poses any new concerns of safety and effectiveness, and comparison shows, that Renamel® Microfill is substantially equivalents to the predicate Renamel® Composite Resin (K854755).