



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

November 17, 2015

Nanova Biomaterials, Inc.
Mr. Andrew Ritts
Senior Research Scientist
3806 Mojave Ct
Columbia, Missouri, 65202

Re: K152004

Trade/Device Name: Nanova™ Universal Dental Composite
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth shade resin material
Regulatory Class: II
Product Code: EBF
Dated: October 12, 2015
Received: October 19, 2015

Dear Mr. Ritts:

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" (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 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 yours,

 Tina
Kiang -S

for Erin I. Keith, M.S.

Director

Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure



Nanova Biomaterials, Inc.
Nanova™ Universal Dental Composite
Dental Composite
510(k) Notification

Section 4. Indications for Use Statement

(As Required by 21 CFR 807.87(e))

510(k) Number (if known): K152004

Device Name: Nanova™ Universal Dental Composite

Indications for Use:

Nanova Universal Dental Composite is indicated for use in:

- Direct anterior and posterior restorations (including occlusal surfaces)
- Core Build-ups
- Splinting
- Indirect restorations including inlays, onlays and veneers

Prescription Use X

AND/OR

Over-The-Counter Use

(Part 21 CFR 801 Subpart D)

(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)



Nanova Biomaterials, Inc.
 Nanova™ Universal Dental Composite
 Dental Composite
 K152004

Section 5. 510(k) Summary

- 1) **Submitted By:**
 Nanova Biomaterials, Inc
 3806 Mojave Ct
 Columbia, MO 65202
 USA
 573-875-6682

 Contact Person: Andrew Ritts Phone: (573) 823-3114
 Secondary Contact: Liang Chen Phone: (573) 239-8952
- 2) **Establishment Registration No.:** 3011430871
- 3) **Date Prepared:** October 12, 2015
- 4) **Device Trade Name:** **Nanova™** Universal Dental Composite
- 5) **Device Common Name:** Universal Dental Composite
- 6) **Device Classification Name:** Material, Tooth Shade, Resin
 Product code: EBF, Reg. #: 872.3690
- 7) **Classification Panel:** Dental
- 8) **Device Class:** Class II
- 9) **Predicate Devices:**
Nanova™ Universal Dental Composite is believed to be substantially equivalent to the following marketed products: Filtek Supreme Ultra Universal Restorative (K083610) product code EBF manufactured by 3M ESPE.
- 10) **Indication for Use:**
 Nanova Universal Dental Composite is indicated for use in:
 - Direct anterior and posterior restorations (including occlusal surfaces)
 - Core Build-ups
 - Splinting
 - Indirect restorations including inlays, onlays and veneers

Section 5. 510(k) Summary - Cont.11) Device Description:

Nanova™ Universal Dental Composite is a methacrylate based, visible-light activated, radiopaque, universal composite. This device is available in twist syringe and ampule packaging. **Nanova™** Universal Dental Composite is available in a variety of tooth colored shades. **Nanova™** Universal Dental Composite contains methacrylate resins, photo-initiator, and inorganic filler material. Inorganic filler loading is approximately 77% by weight.

When irradiated by light, the methacrylate functionalities of the resins and surface-treated fillers undergo, in conjunction with the photo-initiator system, a light-induced polymerization to form a hard composite that is bonded to the tooth structure with a permanent dental adhesive.

Nanova™ Universal Dental Composite formulation is based off of several FDA approved commercially available universal dental composites. The formulation was modified to improve physical properties, such as flexural strength, and handling properties. As a result of the reformulation, a biocompatibility assessment was developed for **Nanova™** Universal Dental Composite using standard risk assessment techniques and consideration of FDA & International Standards, including ISO 10993 Parts 5 and 10.

12) Substantial Equivalence:

The document, "Guidance on the CDRH Premarket Notification Review Program, 6/30/86 (K86-3)" was used to determine substantial equivalence:

a) The applicant device has the same intended use as the 510(k) cleared predicate listed above.

b) The technological characteristics of this product are believed to be substantially equivalent as those for the predicate device and other methacrylate based products currently on the market. Table 5.1 below shows a comparison of **Nanova™** Flowable Composite and the predicate.

Section 5. 510(k) Summary - Cont.

Table 5.1 Technical Comparison of Nanova™ Universal Dental Composite and Filtek Supreme Ultra Universal Restorative (K083610)

Name	Nanova™ Universal Dental Composite	Filtek Supreme Ultra Universal Restorative (K083610)	Comparison
Indications for use	Direct anterior and posterior restorations (including occlusal surfaces) Core Build-ups Splinting Indirect restorations including inlays, onlays and veneers	Direct anterior and posterior restorations (including occlusal surfaces) Core Build-ups Splinting Indirect restorations including inlays, onlays and veneers	Indicated for the same purposes
Composition	Methacrylate resins, photo-initiators, inorganic fillers	Methacrylate resins, photo-initiators, inorganic fillers	Chemistries are similar
Flexural Strength	ISO 4049:2009 (E)	ISO 4049:2009 (E)	Both above 100 MPa
Compressive Strength	ADA specification 27	ADA specification 27	Both above 300 MPa
Depth of Cure	Passes ISO 4049:2009(E)	Passes ISO 4049:2009(E)	Passed
Water Sorption	ISO 4049:2009 (E)	ISO 4049:2009 (E)	Nanova Less Adsorption
Water Solubility	ISO 4049:2009 (E)	ISO 4049:2009 (E)	Nanova Less Solubility
Packaging	Twist Syringe and Ampule	Twist Syringe and Ampule	Both use twist syringe and ampules

Nanova™ Universal Dental Composite fulfilled ISO 4049 requirements as well as FDA’s guidance ucm071576 Dental Composite Resin Devices. The strength and physical properties show Nanova™ Universal Dental Composite performs equivalently to the predicate device. ISO 10993 biocompatibility (including cytotoxicity, irritation, and sensitization) confirms the material is biocompatible. The fulfillment of ISO 4049 and ISO 10993 show Nanova Universal Dental Composite is substantially equivalent to the predicate.

These differences do not affect the equivalence.

13) Non-Clinical Performance Testing:

Non-clinical and biological testing was completed to assess its performance and biocompatibility to support substantial equivalence. The data provided in this 510(k) submission shows that the composition is biocompatible based on the biocompatibility assessment conducted based on ISO 10993 and benchtop assessment based on UCM071631, ADA specification 27, and ISO 4049. All biocompatibility tests completed were passed.

Table 5.2 List of Tests Completed on Nanova™ Universal Composite

Name	Result
Radiopacity Evaluation	Passed
Color Stability	Passed
Flexural Strength	Passed
Compressive Strength	Passed
Depth of Cure	Passed
Microtensile Strength	Passed
Water Sorption and Solubility	Passed
Knoop Hardness	Passed
Double Bond Conversion (Degree of Conversion)	Passed
ISO Agarose Overlay Using L-929 Mouse Fibroblast Cells	Passed
ISO Intracutaneous Irritation Test	Passed
ISO Guinea Pig Maximization Sensitization Test	Passed
ISO MEM Elution Using L-929 Mouse Fibroblast Cells	Passed
Shelf life	Passed
Surface Gloss	Passed
Surface Roughness	Passed

14) Clinical Performance Testing:

Clinical performance data was not included.

Conclusion:

Nanova Biomaterials Inc. believes that **Nanova™** Universal Dental Composite is substantially equivalent to currently legally marketed products. It does not introduce new indications for use, has similar technological characteristics and does not introduce new potential hazards or risks.