Nanova Biomaterials Inc
Andrew Ritts
Director of Quality System Regulation and Regulatory Affairs
3806 Mojave Ct
Columbia, Missouri 65202

January 16, 2018

Re: K172977
Trade/Device Name: Nanova 2 Step Etch and Rinse Dental Adhesive, Nanova Etchant Gel
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: Class II
Product Code: KLE
Dated: December 19, 2017
Received: December 19, 2017

Dear Andrew 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.

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

forTina 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)*
K172977

Device Name
Nanova 2 Step Etch and Rinse Dental Adhesive

Indications for Use *(Describe)*
Nanova 2 Step Etch and Rinse Dental Adhesive is indicated for use in:
- All direct restorations
- All indirect restorations
- Intra-oral repairs
- Desensitizing/sealing of tooth structure
- Priming of enamel for orthodontic use

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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"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."

510(k) Summary

Submitted By:
Nanova Biomaterials, Inc.
3806 Mojave Ct
Columbia, MO 65202
USA
573-875-6682
Contact Person: Andrew Ritts Phone: (573) 875-6682
Secondary Contact: Liang Chen Phone: (573) 875-6682

Establishment Registration No.:	3011430871
Date Prepared:	December 19, 2017
Device Trade Name:	**Nanova™ 2 Step Etch and Rinse Dental Adhesive**
Device Common Name:	Dental Adhesive
Device Classification Name:	Agent, Tooth Bonding, Resin
Classification Panel:	Dental
Device Class:	Class II
Classification Product Code:	KLE
Regulation Number:	872.3200
Predicated Devices:	Adper Single Bond Plus (K962785)

Indication for Use:

Nanova™ 2 Step Etch and Rinse Dental Adhesive	Adper Single Bond Plus (K962785)
Nanova™ 2 Step Etch and Rinse Dental Adhesive is indicated for use in: • All direct restorations • All indirect restorations • Intra-oral repairs • Desensitizing/sealing of tooth structure • Priming of enamel for orthodontic use	The device is indicated for direct and indirect dental bonding applications; bonding veneers and root desensitization

Both products are indicated for direct bonding, indirect bonding, and desensitization. The predicate includes bonding veneers, which can be placed either with indirect bonding or direct bonding technique. **Nanova™ 2 Step Etch and Rinse Dental Adhesive** include intra oral repairs and orthodontic applications, which are typically direct bonding. Any differences observed do not introduce any new or increased concerns of safety or effectiveness.

Device Description:

Nanova™ 2 Step Etch and Rinse Dental Adhesive is a methacrylate based, visible-light activated, dental adhesive, the same as the predicate. This device is available in bottle or unit dose packaging, the same as the predicate. **Nanova™ 2 Step Etch and Rinse Dental Adhesive** contains ethanol, methacrylate resins, photoinitiator, and inorganic filler material the same as the predicate.

When irradiated by light, the methacrylate functionalities of the resins and surface-treated fillers undergo, in conjunction with the photoinitiator system, a light-induced

polymerization to form a hard sealant that is bonded to the prepared tooth structure. Any differences between the subject device and the predicate do not introduce any introduce any new or increased concerns about safety or effectiveness.

	Nanova™ 2 Step Etch and Rinse Dental Adhesive	Adper Single Bond Plus (K962785)
Composition	Ethanol, methacrylate resins, photo-initiators, inorganic fillers	Ethanol, methacrylate resins, Silica, photo-initiators, inorganic fillers
Packaging	Bottle, Unit Dose	Bottle, Unit Dose
Etch Time	15s etch	15s etch
Cure Time	10s light cure	10s light cure
Bonding	Bonds to dentin, enamel, ceramic, and metal	Bonds to dentin, enamel, porcelain, and metal

Non Clinical Performance:

Non-clinical performance testing conducted is shown in the table below. **Nanova™ 2 Step Etch and Rinse Dental Adhesive** met performance criteria for every test including: shear strength, microtensile strength, water sorption, water solubility, and degree of conversion. Non-clinical comparison testing was based on ISO 29022, ISO 4049, and internal specifications. A comparison is shown in the table below.

Property	**Standard**	**Nanova™ 2 Step Etch and Rinse Dental Adhesive**
Shear Bond Strength	ISO 29022:2013	Met internal performance criteria
Micro-Tensile Strength	Internal specifications	Met internal performance criteria
Water Sorption	ISO 4049:2009	Met internal performance criteria
Water Solubility	ISO 4049:2009	Met internal performance criteria
Degree of Conversion	Internal specification	Met internal performance criteria

Biocompatibility:

Nanova™ 2 Step Etch and Rinse Dental Adhesive completed a risk assessment covering the identification of legally marketed devices for all ingredients in the chemical composition and testing including: cytotoxicity (ISO 10993-5), irritation (ISO 10993-10), sensitization (ISO 10993-10), and acute systemic toxicity (ISO 10993-11).

Clinical Performance Testing:

Clinical performance data was not conducted.

Conclusion:

Nanova Biomaterials Inc. believes that **Nanova™ 2 Step Etch and Rinse Dental Adhesive** is substantially equivalent to currently legally marketed products. Product based on comparison of similar intended use and technology together with the non-clinical performance testing. Any differences do not raise different questions of safety and effectiveness than the predicate, nor do they affect the safety or effectiveness of the subject device. These differences therefore do not render the new device NSE in comparison to the predicate.