September 24, 2019

Nobio Ltd.
% Shoshana (Shosh) Friedman
Senior Regulatory Consultant
Nobio [c/o ProMedoss, Inc.]
3521 Hatwynn Rd.
Charlotte, North Carolina 28269

Re: K183391
Trade/Device Name: Novidia Universal Bond
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: Class II
Product Code: KLE
Dated: June 24, 2019
Received: June 26, 2019

Dear Shoshana (Shosh) Friedman:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael Adjodha
Acting Assistant Director
DHT1B: Division of Dental Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183391

Device Name
Novidia™ Universal Bond

Indications for Use *(Describe)*

Novidia Universal Bond is indicated for:

1) Direct restorations using light-cured composite resin or compomer
2) Cavity sealing as a pretreatment for indirect restorations
3) Treatment of hypersensitive teeth and/or exposed root surfaces
4) Intraoral repairs of fractured crowns/bridges made of porcelain, hybrid ceramics, or composite resin using light-cured composite resin
5) Surface treatment of prosthetic appliances made of porcelain, hybrid ceramics, or cured composite resin
6) Core build-ups using light- or dual-cured composite resin
7) Cavity sealing under amalgam restorations

* For indications 1, 2, 3, 6, and 7 the device exhibits an antibacterial cavity cleansing effect.

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.

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510(K) SUMMARY

[as required by section 807.92(c)]

Novidia™ Universal Bond

510(k) Number K183391

5.1 SUBMITTER

Applicant's Name:
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Contact Person:
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Phone: 704-430-8695
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Date Prepared:
January 3, 2019

5.2 DEVICE

Trade Name:
Novidia™ Universal Bond

Classification Code:
Name: Agent, Tooth Bonding, Resin
Product Code: KLE
Regulation No: 872.3200
Class: 2
Review Panel: Dental

5.3 PREDICATE DEVICE

- Primary predicate device: CLEARFIL™ Protect Bond, manufactured by Kuraray Medical Inc., cleared under K023842 and K033938
- Reference device: 3M™ ESPE™ Adper™ Scotchbond™ multi-purpose, manufactured by 3M Company, cleared under K920424 and K942493

5.4 DEVICE DESCRIPTION

Novidia™ Universal Bond is a resin-based bond system consisting of a self-etch primer and a light-cured bond. It is designed to enhance penetration into prepared

enamel and dentin surfaces and to establish strong adhesion between mineralized dental surfaces and the restorative materials such as resin composites, resin cements, metals, and ceramics (e.g., porcelain, lithium disilicate, zirconia, or hybrid ceramics) restorations.
The chemical composition of the Universal Bond's primer consists of adhesion promoter and solvent, and the Universal Bond consists of resin, solvent, initiators and antibacterial insoluble particles, which contain covalently bound quaternary ammonium (QA).

5.5 INDICATIONS FOR USE

Novidia™ Universal Bond is indicated for use in:

1) Direct restorations using light-cured composite resin or compomer
2) Cavity sealing as a pretreatment for indirect restorations
3) Treatment of hypersensitive teeth and/or exposed root surfaces
4) Intraoral repairs of fractured crowns/bridges made of porcelain, hybrid ceramics, or composite resin using light-cured composite resin
5) Surface treatment of prosthetic appliances made of porcelain, hybrid ceramics, or cured composite resin
6) Core build-ups using light- or dual-cured composite resin
7) Cavity sealing under amalgam restorations

** For indications 1, 2, 3, 6, and 7 the device exhibits an antibacterial cavity cleansing effect.

5.6 SUBSTANTIAL EQUIVALENCE

The Novidia Universal Bond has the same intended use and substantially similar technological characteristics as the Clearfil Protect Bond primary predicate device and its performance characteristics is substantially similar to both the Clearfil Protect Bond and the Adper Scotchbond reference device.

The general comparison between the Novidia Universal Bond, Clearfil Protect Bond and Adper Scotchbond are provided in Table 5-1 and the performance comparison between the devices are provided in Table 5-2 below.

Table 5-1: General Comparison between Novidia Universal Bond, Clearfil Protect Bond and Adper Scotchbond

Element	Subject Device: Novidia Universal Bond	Primary Predicate Device: Clearfil SE Protect Bond	Reference Device: 3M Adper Scotchbond
Manufacturer	Nobio, Ltd.	Kuraray Medical, Inc.	3M ESPE Dental Products
510(k) Number	K183391	K033938	K942493
Product Code	KLE	KLE	KLE
Indications for Use	1) Direct restorations using light-cured composite resin or compomer 2) Cavity sealing as a pretreatment for indirect restorations 3) Treatment of hypersensitive teeth and/or exposed root surfaces 4) Intraoral repairs of fractured crowns/bridges made of porcelain, hybrid ceramics, or composite resin using light-cured composite resin 5) Surface treatment of prosthetic appliances made of porcelain, hybrid ceramics, or cured composite resin 6) Core build-ups using light- or dual-cured composite resin 7) Cavity sealing under amalgam restorations ** For indications 1, 2, 3, 6, and 7 the device exhibits an antibacterial cavity cleansing effect.	1) Direct restorations using light-cured composite resin or compomer 2) Cavity sealing as a pretreatment for indirect restorations 3) Treatment of hypersensitive and/or exposed root surfaces 4) Intraoral repairs of fractured crowns/bridges made of porcelain, hybrid ceramics, or composite resin using light-cured composite resin 5) Surface treatment of prosthetic appliances made of porcelain, hybrid ceramics, or cured composite resin 6) Core build-ups using light- or dual-cured composite resin 7) Cavity sealing under amalgam restorations ** For indications 1, 2, 3, 6, and 7 the device exhibits an antibacterial cavity cleansing effect.	Bonding all classes of direct composite restorations as well as bonding porcelain veneers, porcelain and composite repairs with light cure composite and bonding light cure composite to amalgam.
Components	Primer and Bond	Primer and Bond	Etchant, Primer and Adhesive

Element	Subject Device: Novidia Universal Bond	Primary Predicate Device: Clearfil SE Protect Bond	Reference Device: 3M Adper Scotchbond
Composition of Primer	Adhesive monomer carried in a water-ethanol solution	Adhesive monomer carried in a water-ethanol solution	Aqueous solution of HEMA and a polyalkenoic acid copolymer
Composition of Bond (Adhesive)	Matrices of hydrophilic, hydrophobic and amphiphilic nature	Matrices of hydrophilic, hydrophobic and amphiphilic nature	Matrices of hydrophilic, hydrophobic and amphiphilic nature
Antibacterial Component	Quaternary Ammonium Silica (QASi)	12-methacryloyloxy-dodecyl-pyridinium-bromide (MDPB)	None
Mode of Use	Two-steps using two bottles of components, the first containing a self-etching primer and the second the bonding agent.	Two-steps using two bottles of components, the first contains a self-etching primer and the second contains the bonding agent.	Three-steps using three bottles, the first contains an etchant, the second contains a primer, and the third contains the bonding (adhesive) agent.
Self-Etching	Yes	Yes	No
Light-Cured	Yes	Yes	Yes
Curing Wavelength	430-490nm	400-515nm	Unknown
Curing Time	10 seconds	10 seconds	10 seconds

Table 5-2: Performance Comparison between Novidia Universal Bond, Clearfil Protect Bond and Adper Scotchbond

Test		Acceptance Criteria	Novidia Universal Bond	Clearfil Protect Bond	3M Adper Scotchbond
Polymerization Conversion Degree		≥70%	Passed	Passed	Passed
Viscosity		550±450 cP	Passed	Passed	Passed
Shear Bond Strength	Zirconia	≥ 10 MPa	Passed	Passed	Passed
	Glass Ceramics		Passed	Passed	Passed
	Enamel		Passed	Passed	Passed
	Dentin		Passed	Passed	Passed
	Titanium		Passed	Passed	Passed
	Composite		Passed	Passed	Passed
	Amalgam	≥ 7 MPa	Passed	Passed	Passed
Micro Leakage		Penetration levels: 0 (no penetration) to 1 (only shallow enamel surface penetration).	Passed	Passed	Passed
Antibacterial Activity		Reduction of the viable bacteria	Passed	Passed	NA

5.7 PERFORMANCE DATA

Non-Clinical Performance Testing:

Non-clinical and biological testing was completed to assess the performance and biocompatibility of the Novidia™ Universal Bond and to support substantial equivalence. The data provided in this 510(k) submission shows that the bonding agent is biocompatible based on the biocompatibility assessment conducted as per ISO 10993 and ISO 7405 and performs as intended based on the bench testing. The list of these tests is provided in Table 5-3.

Table 5-3: List of Tests Completed on Novidia Universal Bond

Biocompatibility
Cytotoxicity
Acute Systemic Toxicity
Direct Buehler Sensitization Test
Oral Irritation Test
Chemical Characterization
Material Mediated Pyrogenicity
Biological Risk Assessment
Bench Testing
Polymerization Conversion Degree
Viscosity
Shear Bond Strength • Zirconia • Glass Ceramics • Enamel • Dentin • Titanium • Composite • Amalgam
Visual Inspection
Micro Leakage
Antibacterial Activity

Animal and Clinical Performance Testing:

Animal and clinical performance data was not included.

5.8 CONCLUSION

Nobio Ltd. believes that Novidia™ Universal Bond is substantially equivalent to the Clearfil Protect Bond primary predicate device and the 3M Adper Scotchbond reference device. It does not introduce new indications for use, has substantially equivalent technological and performance characteristics, and therefore does not introduce any new safety or effectiveness concerns.