January 19, 2021

Imicryl Dis Malzemeleri Sanayi Ve Ticaret A.S.
Husamettin Sonmez
General Manager
Fetih Mahallesi Mahir Sokak No:5/201
Konya, 42030 TURKEY

Re: K192913
Trade/Device Name: R&D Series Nova Compo-B Plus Bottle, R&D Series Nova Compo-B Plus Single Dose
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: Class II
Product Code: KLE
Dated: December 15, 2020
Received: December 21, 2020

Dear Husamettin Sonmez:

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 E. Adjodha, M.ChE.
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)*
K192913

Device Name
R&D Series Nova Compo-B Plus

Indications for Use *(Describe)*
1. Direct restorations using light-cured composite resin
2. Cavity sealing as a pretreatment for indirect restorations
3. Treatment of exposed root surfaces
4. Treatment of hypersensitive teeth
5. Intraoral repairs of fractured restorations
6. Post cementation and core build-ups
7. Cementation of inlays, onlays, crowns, bridges and veneers

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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K192913

510(k) Summary

R&D Series Nova Compo-B Plus ®

All in One Universal Adhesive

Date of Summary Preparation: September 05, 2019

Type of Submission: Traditional 510(k)

Submitter Information:

Company Name: IMICRYL DIS MALZEMELERI SANAYI VE TICARET A.S.

Company Address: Fetih Mahallesi Mahir Sokak No:5/201 Zip Code:42030 Karatay/Konya/TURKEY

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Secondary Contact Person: Muhammed Hulusi SONMEZ

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Device Information:

Trade Name: R&D Series Nova Compo-B Plus

Common Name: Dental Bonding Agent

Product Code: KLE

Classification Class: II

Classification Name: Resin Tooth Bonding Agent

Regulation Number: 872.3200

Review Panel: Dental

Predicate and Reference Devices:

R&D Series Nova Compo-B Plus all in one universal adhesive is substantially equivalent to

the following marketed products:

COMPANY	DEVICE	510(k) NUMBER	PRODUCT CODE
GC America Inc.	G-Premio BOND **(Reference Device)**	K143140	KLE
Kuraray Noritake Dental Inc.	CLEARFIL Universal Bond **(Predicate Device)**	K132450	KLE

Indication for Use:

1. Direct restorations using light-cured composite resin
2. Cavity sealing as a pretreatment for indirect restorations
3. Treatment of exposed root surfaces
4. Treatment of hypersensitive teeth
5. Intraoral repairs of fractured restorations
6. Post cementation and core build-ups
7. Cementation of inlays, onlays, crowns, bridges and veneers

Device Description:

R&D Series Nova Compo- B Plus is a Light-cure ethanol/water-based, self-etching, one-step, all in one universal adhesive. It can be used reliably in total-etch, self-etch or selective-etch mode for both direct and indirect restorations. Depending on the indication, the adhesive is used as self-etching or with phosphoric acid for selective enamel etching or total-etching procedures. The product is intended to be used for both direct and indirect restorations. The 4-MET RDX multi-functional carboxylate methacrylate polymer creates a 3-dimensional, high-strength bond with calcium. MDP (Methacryloyloxydecyl Dihydrogen Phosphate) monomer binds to Ca+2 ions on all surfaces of the tooth. The R&D Series Nova Compo- B Plus forms a micro-mechanical bond between the dentine channels to form the resin tags. Depending on the indication, the adhesive is used as self-etching or with phosphoric acid for selective enamel etching or total-etching procedures.

This is the new registration application for the subject device and there have not been any prior submissions regarding the subject device and there have not been any prior submissions regarding the subject device.

The product is sold in 5 ml bottles or 50x0.1 ml capsule.

Substantial Equivalence:

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

Table 1 below shows a comparison of R&D Series Nova Compo-B Plus all in one universal adhesive and the predicate and reference devices.

DESCRIPTIVE INFORMATION	NEW DEVICE/ R&D SERIES NOVA COMPO B PLUS	REFERENCE DEVICE/ G-Premio BOND (K143140)	PREDICATE DEVICE/ Clearfil Universal Bond (K132450)
INDICATION FOR USE			
	1. Direct restorations using Light-cured composite resin 2. Cavity sealing as a pretreatment for indirect restorations 3. Treatment of exposed root surfaces 4. Treatment of hypersensitive teeth 5. Intraoral repairs of fractured restorations 6. Post cementation and core build-ups 7. Cementation of inlays, onlays, crowns, bridges and veneers	1. Bonding of light cured composites and acid modified composites (compomers) to tooth structure. 2. Bonding of dual cured luting and core build up composites to tooth structure as long as these materials are light cured. 3. Intraoral repairs of porcelain fused to metal crowns and composite veneer crowns with metal backing. 4. Intraoral repairs of all ceramic crowns (except zirconia and alumina), hybrid resin jacket crowns, CAD/CAM hybrid resin crowns and composites. 5. Intraoral repairs of porcelain fused to zirconia crowns, porcelain fused to alumina crowns and full zirconia crowns. 6. Treatment of hypersensitive teeth.	1. Direct restorations using light-cured composite resin 2. Cavity sealing as a pretreatment for indirect restorations 3. Treatment of exposed root surfaces 4. Treatment of hypersensitive teeth 5. Intraoral repairs of fractured restorations 6. Post cementation and core build-ups 7. Cementation of inlays, onlays, crowns, bridges and veneers
COMPOSITION			

	• Hydrophilic aliphatic dimethacrylate • 2 hydroxyethyl methacrylate (HEMA) • Bis-GMA • MDP monomer (10-Methacryloyloxy decyl dihydrogen phosphate), • 4- MET RDX multi-functional carboxylate methacrylate polymer • Silane • Ethanol • Water • Highly dispersed silicon dioxide (10%), • dl-camphoroquione • Stabilizers	• Acetone • 2-Hydroxy-1,3 dimethacrylaxypro pane • 10-Methacryloyloxyde cyl dihydrogen phosphate (MDP) • 2,2-ethylenedioxydieth yl dimethacrylate • Diphenyl (2,4,6 trimethylbenzoyl) phosphine oxide • 4- MET RDX multi-functional carboxylate methacrylate polymer • dl-camphoroquione • 2,6 di-tert-butyl-p-cresol(Stabilizers)	• 10-Methacryloyloxydecyl dihydrogen phosphate (MDP) • Bisphenol A diglycidylmethacrylate (Bis-GMA) • 2-Hydroxyethyl methacrylate (HEMA) • Hydrophilic aliphatic dimethacrylate • Colloidal silica • 4- MET RDX multi-functional carboxylate methacrylate polymer • Silane coupling agent • dl-Camphorquinone • Ethanol • Water • Stabilizers
PHYSICAL PROPERTIES			
Appearance	Homogenous and free from foreign matters	Homogenous and free from foreign matters	Homogenous and free from foreign matters
Curing Time	10 second	10 second	10 second
Bond strength to tooth structure	>10 MPa for enamel	>10 MPa for enamel	>10 MPa for enamel
	>10 MPa for dentin	>10 MPa for dentin	>10 MPa for dentin
Bond strength to metal	>10 MPa for precious metal	>10 MPa for precious metal	>10 MPa for precious metal
	>10 MPa for non-precious metal	>10 MPa for non-precious metal	>10 MPa for non-precious metal
Bond strength to ceramic and composite	>10 MPa for porcelain	>10 MPa for porcelain	>10 MPa for porcelain
	>10 Mpa for composite	>10 Mpa for composite	>10 Mpa for composite
	>10 MPa for zirconia	>10 MPa for zirconia	>10 MPa for zirconia

Similarities

- The intended uses of the subject device were written up based on those of CLEARFIL UNIVERSAL BOND. Therefore, the intended uses of the subject device are substantially equivalent to those of the predicate devices.
- Products; they are substantially equivalent in terms of their physical properties.
- The specifications that are important to determine substantial equivalency of a dental adhesive system are bond strengths associated to enamel and dentin (tooth structure). The bond strengths as noted above compare the predicate device to the new device. In both enamel and dentin bonding, the results were equivalent.
- Due to its similarity in the G-Premio Bond formulation, it is the reference device of R&D Series Nova Compo B Plus.
- All ingredients in the subject have been used in the predicate devices.
  Regarding the predicate devices, there have not been any reported problems or recalls according to the post-market adverse event reporting requirements in the US.
  Accordingly, it was concluded that the safety of the subject device was substantially equivalent to that of the predicate devices.
- As the result of the testings, it was confirmed that the performance of the subject device was not significantly different or not less than that of the predicate devices.

Differences

- Even if it seems like a difference; The Colloidal silica contained in Kuraray Clearfil Universal Bond is the same as our highly dispersed silicon dioxide (10%) contain.
- Clearfil Universal Bond and R & D Series Nova Compo-B plus products use ethanol as a solvent, while Acetone is used in G-Premio products. Ethanol and acetone are being used as a solvent in the bonding agents. Before light curing the bonding agent, the solvent is evaporated with air by dentist. The solvent does not affect the adhesive strength of the bonding agents because it is removed during application.
- Clearfil Universal Bond and R & D Series Nova Compo-B plus products use META as a monomer, G-Premio use 2-Hydroxy-1,3 dimethacrylaxypropane. These monomers are similar monomers.
- Clearfil Universal Bond and R & D Series Nova Compo-B Plus products do not require primers in ceramic restorations because they contain silane, but because G-Premio does not contain silane, they require primers in ceramic restorations.

Non-Clinical Performance Testing:

Biocompatibility Testing:

In accordance with 10993-1 (Biological Assessment Medical Devices- Part1:Evaluation and Testing) and ISO 7405 (Dentistry – Biocompatibility of Medical Devices used in Dentistry) standards, biocompatibility was evaluated for R&D Series Nova Compo-B Plus all in one universal adhesive. The biocompatibility data for R&D Series Nova Compo-B Plus all in one universal adhesive are given in the table below.

TEST NAME	RESULT
Cytotoxicity	After 24 hours, severe (+4) degree of biological reactivity was observed.
Sensitization	Does not cause hypersensitive skin reaction.
Skin Irritation	Does not cause skin irritation.
Acute Systemic Toxicity	Does not have acute systemic toxic effects.
Subacute Systemic Toxicity	Does not have subacute systemic toxic effects.
Genotoxicity	Does not have genotoxic potential.
Implantation	According to local effect categories after implantation for rabbit, "mild irritation was found to be effective."

The subject device is categorized into the external communicating device (tissue/bone/dentin) and permanent contact device.
All the chemical ingredients of the subject device are equivalent to those of the predicate devices.
Regarding the predicate devices, there have not been any reported problems or recalls according to the post-market adverse event reporting requirements in the US.
Accordingly, it was concluded that the subject device was substantially equivalent in safety to the predicate devices.

Physical Properties:
In vitro bench tests were performed on the R&D Series Nova Compo-B Plus all in one universal adhesive according to the requirements in ISO 29022:2013 Dentistry-Adhesion-Notched-edge shear bond strength test.

Bench tests included in support of the substantial equivalence of R&D Series Nova Compo-B Plus all in one universal adhesive are:

- Appearance
- Curing Time
- Bond Strength to Tooth Structure
- Bond Strength to Metal
- Bond Strength to Ceramic and Composite

Technological Characteristics:

The chemical composition of the subject device is such that it can bond to tooth surfaces as well as composites, hybrid ceramics, ceramics and metals.

Conclusion:

In accordance with the Federal Food, Drug and Cosmetic Act and 21 CFR Part 807, and based on the information provided in this premarket notification, IMICRYL DIS MALZEMELERI SANAYI VE TICARET A.S. concludes that the R&D SERIES NOVA COMPO-B PLUS all in one universal adhesive is safe, effective and substantially equivalent to the predicate device and reference device as described herein. It does not introduce new indications for use, has similar technological characteristics and does not introduce new potential hazards or risks.