December 20, 2019

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

Re: K192178
Trade/Device Name: R&D Series Nova Compo N
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth shade resin material
Regulatory Class: Class II
Product Code: EBF
Dated: October 1, 2019
Received: October 7, 2019

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,

for Srinivas “Nandu” Nandkumar, Ph.D.
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)*

K192178

Device Name

R&D Series Nova Compo N

Indications for Use *(Describe)*

R&D Series Nova Compo N is a light–curing, radiopaque, nano–hybrid universal composite for anterior and posterior restorations. It is intended for professional use by below mentioned Indications for Use;

· Restorations of deciduous teeth
· Splinting of mobile teeth
· Restoration in the posterior region (Classes I and II)
· Anterior restorations (Classes III, IV)
· Class V restorations (cervical caries, root erosion, wedge-shaped defects)
· Extended fissure sealing in molars and premolars
· Veneering of discoloured anterior teeth
· Repair of composite and ceramic 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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K192178

510(k) Summary

R&D SERIES NOVA COMPO N®
Light Cure Nano Hybrid Composite

Date of Summary Preparation: July 17, 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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Device Information:

Trade Name: R&D SERIES NOVA COMPO N®

Common Name: Light Cure Nano Hybrid Composite

Product Code: EBF

Classification: Class II

Classification Name: Tooth Shade Resin Material

Regulation Number: 872.3690

Review Panel: Dental

Predicate Devices:

R&D Series Nova Compo N light cure nano hybrid composite is substantially equivalent to the following marketed products:

COMPANY	DEVICE	510(k) NUMBER	PRODUCT CODE
Ivoclar Vivadent, Incorporated	Tetric Evoceram	K042819	EBF
Kuraray Medical, Inc.	Clearfil Majesty Esthetic	K061860	EBF

Indication for Use:

R&D Series Nova Compo N is a light-curing, radiopaque, nano-hybrid universal composite for anterior and posterior restorations. It is intended for professional use by below mentioned Indications for Use;

- Restorations of deciduous teeth
- Splinting of mobile teeth
- Restoration in the posterior region (Classes I and II)
- Anterior restorations (Classes III, IV)
- Class V restorations (cervical caries, root erosion, wedge-shaped defects)
- Extended fissure sealing in molars and premolars
- Veneering of discoloured anterior teeth
- Repair of composite and ceramic veneers

Device Description:

R&D Series Nova Compo N is a light-curing, radiopaque, nano hybrid composite for anterior and posterior restorations.
According to the applicable FDA recognized consensus standard: ISO 4049:2009 "Dentistry-Polymer Based Restorative Materials", this device is classified into the following:
-Type 1: polymer-based filling and restorative materials;
-Class 2: Materials whose setting is effected by light;
-Group 1: Materials whose use requires the energy to be applied intra-orally.
R&D Series Nova Compo N light cure nano hybrid composite is designed with the high molecular weight reduced shrinkage resin. The higher molecular weight of the resin results in less shrinkage, reduced aging and a slightly softer resin matrix. Additionally these resins impart a greater hydrophobicity and are less water absorption. Prepolymerized fillers provide low shrinkage, low stress, non-sticky, easy handling and shaping formulation. High loading Prepolymerized fillers provide better wear resistance than traditional less loaded Prepolymerized fillers in other marketing composites. The nanofillers provide high polish, high wear, surface hardness and making the material smooth.
R&D Series Nova Compo N light cure nano hybrid composite was tested for biocompability and found to be biocompatible as a result of testing.

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 N light cure nano hybrid composite and the predicates.

Table 1

DESCRIPTIVE INFORMATION	NEW DEVICE/R&D SERIES NOVA COMPO N Light cure nano hybrid composite	PREDICATE/TETRIC EVOCERAM	PREDICATE/CLEARFILL MAJESTY ETSHETIC
INDICATION FOR USE			
	• Restorations of deciduous teeth • Splinting of mobile teeth • Restorations in the posterior region (classes I and II) • Anterior restorations (classes III, IV)	• Restorations in the posterior region (Classes I and II) • Anterior restorations (Classes III, IV) • Class V restorations (cervical caries, root erosion, wedge-shaped defects) • Veneering of discoloured	• Direct restorations for all cavity classes in anterior and posterior teeth • Direct veneers • Correction of tooth position and tooth shape (e.g. diastema closure, dwarfed tooth, etc.)

	• Class V restorations (cervical caries, root erosion, wedge–shaped defects) • Extended fissure sealing in molars and premolars • Veneering of discoloured anterior teeth • Repair of composite and ceramic veneers	anterior teeth • Splinting of mobile teeth • Repair of composite/ceramic veneers	• Intraoral repairs of fractured restorations
COMPOSITION			
	The monomer matrix is composed of Bis–GMA, hydrophobic aromatic dimethacrylates, UDMA, Bis–EMA, The fillers contain barium glass, ytterbium trifluoride, nano filler and prepolymer as an organic filler and inorganic filler. dl-Camphorquinone additives, initiators, stabilizers Accelerators Pigments.	The monomer matrix is composed of dimethacrylates. The fillers contain barium glass, ytterbium trifluoride, mixed oxide and copolymers. Additives, Initiators, Stabilizers Pigments Urethane dimethacrylates, Bis-GMA, Ytterbium trifluoride, Ethyoxylated bisphenol A dimethacrylates (Bis-EMA) dl-Camphorquinone	Silanated barium glass filler. Pre-polymerized organic filler including nano filler Bis-phenol A diglycidyl methacrylate (Bis-GMA) · Hydrophobic aromatic dimethacrylate · dl-Camphorquinone · Initiators, Accelerators Pigments YbF3(Ytterbium trifluoride)
PHYSICAL PROPERTIES			
Compressive Strength (MPa)	360	250	356
Flexural Strength (MPa)	130	120	118
Depth Of Cure (mm)	≥2	>1,5	>1,5
Particle Size Range	40 nm and 3 µm.	Particle Size Range: 40nm-3micron	Particle Size Range: 20nm-3micron
Water Sorption (µg/mm3)	21,2	21,2	25,3
Water Solubility (µg/mm3)	< 1,0	< 1,0	<1,5
Elastic Modulus	10 GPa	10 GPa	10 GPa
Radio-opacity (mm of Al)	%350	%400	%180
Working Time (second)	250	200	250
Curing Time (second)	20	20	20
Sensitivity to Ambient Light (second)	250	200	250
Color stability	YES	YES	YES

Similarities

- Tetric Evo Ceram, Clearfil Majesty and Nova Compo N are light cured glass filled nano hybrid composites. All devices have the same basic structure. The basic structures are glass fillers and methacrylate resins.
- Tetric Evo Ceram and Nova Compo N contain the same resin matrix. The resin matrix is UDMA (Urethane Dimethacrylate), Bis-GMA, Bis-EMA (Ethoxylated bisphenol-A dimethacrylate) and dl-comphoroquione. Clearfil Majesty and Nova Compo N have similar resin matrix. The similar resins are Bis-gma, hydrophotic aromatic dimethacrylate, dl-comphoroquione.

- All devices have inorganic (ba-glass etc.) and organic fillers (prepolymers, copolymers). Tetric Evo Ceram, Nova Compo N and Clearfil Majesty are containing organic fillers. But the organic fillers are called prepolymer in Nova Compo N, Clearfil Majesty and copolymer in Tetric Evo Ceram. Basically prepolymer and copolymers mean the same material. Prepolymers are being used in composite formulations to reduce the polymerization shrinkage and improve the handling properties. Prepolymer and copolymers: The composite resins and fillers are mixed, moulded, polymerized and grind to small particles. As a result sometimes the material is called prepolymer or copolymer. Copolymer is a prepolymer. Because prepolymer is produced from different base materials.
- All devices contain ba-glass, ytterbium triflouride for radiopacity as inorganic filler.
- Nova Compo N and Clearfil Majesty also contain nano filler.
- The usage areas and purposes of the products are the same.
- Physical Property data similar to the predicate device.

Differences

- Tetric Evo Ceram contains mixed oxide and Nova Compo N contains nano filler. The aim of both mixed oxide and nano filler materials are improve the surface gloss, increase mechanical properties and to fill the voids of bigger particles.
- Clearfil Majesty does not contain UDMA and Bis-EMA but Tetric Evo Ceram and Nova Compo N contain these monomer. But all devices have similar resin ratio. In Clearfil Majesty Bis-gma and hydrophobic aromatic dimethacrylate are used instead of UDMA and Bis-EMA. But it is not significant because they are both used extensively in Dental composites, have no substantial history of adverse events.

Non-Clinical Performance Testing:

Biocompatibility Testing:

In accordance with ISO 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 N light cure nano hybrid composite.
The biocompatibility data for R & D Series Nova Compo N light cure nano hybrid composite are given in the table below.

TEST NAME	RESULT
In vitro cytotoxicity	Does not have cytotoxic potential
Sensitization	Does not cause sensitivity
Irritation	Does not cause irritation
Acute systemic toxicity	Does not have acute systemic toxic effect
Subacute systemic toxicity	Does not have subacute systemic toxic effect
Genotoxicity	Does not have genotoxic potential
Implantation	Irritant effect was not found

Physical Properties:

In-vitro bench tests were performed on the R&D Series Nova Compo N light cure nano hybrid composite according to the requirements in ISO 4049: 2009 (Dentistry - Polymer-based restorative).
Bench tests included in support of the substantial equivalence of R&D Series Nova Compo N light cure nano hybrid composite are:

• Compressive Strength
• Flexural Strength
•Depth of Cure
• Particle Size Range
• Water Sorption
• Water Solubility
• Elastic Modulus
• Radiopacity
• Working Time
• Curing Time
• Sensitivity to Ambient Light
• Color Stability

The results from bench tests included in this premarket notification support the substantial equivalence of the R&D Series Nova Compo N light cure nano hybrid composite.

Conclusion:

In accordance with the Federal Food, Drug and Cosmetic Act and 21 CFR Part 807, and based on the information provided in this pre-market notification, IMICRYL DIS MALZEMELERI SANAYI VE TICARET A.S. concludes that the R&D SERIES NOVA COMPO N light cure nano hybrid composite is safe, effective and substantially equivalent to the predicate devices as described herein. It does not introduce new indications for use, has similar technological characteristics and does not introduce new potential hazards or risks.