August 9, 2022

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

Re: K213609
Trade/Device Name: NOVA RESIN dual cure, self adhesive resin cement
Regulation Number: 21 CFR 872.3275
Regulation Name: Dental Cement
Regulatory Class: Class II
Product Code: EMA, EBC, EBF
Dated: May 31, 2022
Received: June 6, 2022

Dear Hüsamettin 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 Michael E. Adjodha, M.ChE.
Assistant Director
DHT1B: Division of Dental and
ENT 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)*

K213609

Device Name

NOVA RESIN dual cure, self adhesive resin cement

Indications for Use *(Describe)*

Nova Resin dual cure, self adhesive resin cement is intended for cementation of all indirect restorations including ceramic, resin and metal-based inlays, onlays, bridges, posts and veneers.*
Additional indications include core-buildup material, pit and fissure sealant, and cementation of crowns restorations to implants.
*Adhesive application on the prep is required for veneer cementation using Nova Resin dual cure, self adhesive resin cement.

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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K213609

510(k) Summary

NOVA RESIN

Dual cure, self adhesive resin cement

Date of Summary Preparation: December 28, 2020

Type of Submission: Traditional 510(k)

SUBMITTER INFORMATION:

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

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DEVICE INFORMATION:

Trade Name: NOVA RESIN dual cure, self adhesive resin cement

Common Name: Dental Cement

Primary Product Code: EMA

Secondary Product Code: EBF, EBC

Classification: Class II

Classification Name: Cement, Dental

Regulation Number: 872.3275

Review Panel: Dental

PREDICATE DEVICES:

Nova Resin dual cure, self adhesive resin cement is substantially equivalent to the following marketed product:

COMPANY	DEVICE	510(k) NUMBER	PRODUCT CODE
Kerr Corporation	Maxcem 2	K073209	MZW, EMA

INDICATION FOR USE:

Nova Resin dual cure, self adhesive resin cement is intended for cementation of all indirect restorations including ceramic, resin and metal-based inlays, onlays, bridges, posts and veneers.*

Additional indications include core-buildup material, pit and fissure sealant, and cementation of crowns restorations to implants.

*Adhesive application on the prep is required for veneer cementation using Nova Resin dual cure, self adhesive resin cement.

DEVICE DESCRIPTION:

Resin Cement dual cure, self adhesive resin cement for the cementation of indirect restorations made of high strength all ceramic, composite, metal-ceramic and metal.

When Resin Cement dual cure, self adhesive resin cement is used, additional bonding agents are not required. The automix double syringe enables saving time direct application of the luting cement into restoration.

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 Nova Resin dual cure, self adhesive resin cement and the predicates.

Table 1: Comparison with Predicate Device

DESCRIPTIVE INFORMATION	NEW DEVICE NOVA RESIN Dual Cure, Self Adhesive Resin Cement (K213609)	PREDICATE DEVICE Maxcem2 (K073209)
INDICATIONS FOR USE		
	Nova Resin dual cure, self-adhesive resin cement is intended for cementation of all indirect restorations including ceramic, resin and metal-based inlays, onlays, bridges, posts and	Maxcem 2 is intended for cementation of all indirect restorations including ceramic, resin and metal-based inlays, onlays, bridges, posts and veneers.* Additional indications include core-buildup material, pit and fissure

	veneers.* Additional indications include core-buildup material, pit and fissure sealant, and cementation of crowns restorations to implants. *Adhesive application on the prep is required for veneer cementation using Nova Resin dual cure, self-adhesive resin cement.	sealant, and cementation of crowns restorations to implants. *Adhesive application on the prep is required for veneer cementation using Maxcem2.
PHYSICAL PROPERTIES		
Film Thickness (µm)	17	15
Working Time (sec.)	150	120
Setting Time (min.)	3'10"	3'
Flexural Strength (Mpa)	130	112
Water Sorption (µg/mm^3)	9.8	9.4
Water Solubility (µg/mm^3)	6.9	6.5
Radio-Opacity (mm of Al)	7	6
Compressive Strength (MPa)	360	351
Elastic Modulus (GPa)	4±0.5	4±0.5
Intensity for Curing (second)	10	10
Depth of Cure (mm)	2	1.5
Wavelength for Curing (nm)	470	470
Particle Size (µm)	1.5	2
Surface Hardness (KHN)	7	8
Curing Time (second)	10	10

Similarities

- Nova Resin dual cure, self adhesive resin cement; it is exactly similar to the equivalent device in terms of composition, indications for use, function and physical properties.
- We believe that the prior use of these components in legally marketed devices and the performance data and results support the safety and effectiveness of Nova Resin dual cure, self adhesive resin cement for the intended use.

Differences

- Although the composition amount of the equivalent product is not known exactly, it can be thought that the compositions are the same because the performance test results are the same.

NON-CLINICAL PERFORMANCE TESTING:

Biocompatibility Testing:

In accordance with ISO 10993-1 (Biological Assessment Medical Devices-Part1: Evaluation and Testing) standard, biocompatibility was evaluated for Nova Resin dual cure, self adhesive resin cement. According to the test results, the device; is biocompatible.

Physical Testing:

In-vitro bench tests were performed on the Nova Resin dual cure, self adhesive resin cement according to the requirements in TS EN ISO 4049:2019.

Bench tests included in support of the substantial equivalence of Nova Resin dual cure, self adhesive resin cement are:

- Film Thickness
- Working Time
- Setting Time
- Flexural Strength
- Water Sorption and Solubility
- Radio-opacity
- Compressive Strength
- Elastic Modulus
- Intensity for Curing
- Depth of Cure
- Wavelength for Curing
- Surface Hardness

CONCLUSION

In accordance with the Federal Food, Drug and Cosmetic Act and 21 CFR Part 872.3275, and based on the information provided in this pre-market notification, IMICRYL DIS MALZEMELERI SANAYI VE TICARET A.S. concludes that the Nova Resin dual cure, self adhesive resin cement 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.