



November 2, 2021

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

Re: K210473

Trade/Device Name: Nova Glass Cements (Nova Glass L, Nova Glass F, Nova Glass LC, Nova Glass BF, Nova Glass L Plus)
Regulation Number: 21 CFR 872.3275
Regulation Name: Dental Cement
Regulatory Class: Class II
Product Code: EMA
Dated: September 30, 2021
Received: October 5, 2021

Dear Hüsametttin 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

Indications for Use

510(k) Number (if known)
K210473

Device Name

Nova Glass Cements (Nova Glass L, Nova Glass F, Nova Glass LC, Nova Glass BF, Nova Glass L Plus)

Indications for Use (Describe)

Products

Indications For Use

Nova Glass L

- Cementation of all types of metal, porcelain fused to metal, resin crowns, inlays, onlays & bridges
- Cementation of orthodontic bands
- Cementation of stainless steel crowns or orthodontic appliances retained with stainless steel crowns
- Base/liner

Nova Glass F

- Class III, V and limited class I cavities
- Restoration of primary teeth
- Core Build Up

Nova Glass LC

- Class III and V restorations
- Restoration of Cervical erosions and root surface caries
- Core build up
- Base/liner

Nova Glass BF

- Class I & II cavities
- Deciduous teeth: final restorative for Class I, II and V
- Long term restorative in non-load bearing areas of Class I, II and V
- Intermediate restorative & sandwich material for heavy stress bearing
- Core build up material

Nova Glass L Plus

- Metal-based restorations
- Ceramic inlays
- Reinforced ceramic crowns and bridges
- All kinds of acrylic/resin crowns, inlays, onlays and bridges

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

NOVA GLASS CEMENTS

(NOVA GLASS L, NOVA GLASS F, NOVA GLASS LC, NOVA GLASS BF, NOVA GLASS L PLUS)

Date of Summary Preparation: September 28, 2021

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 Glass Cements (Nova Glass L, Nova Glass F, Nova Glass LC, Nova Glass BF, Nova Glass L Plus)

510(k) Number: K210473

Common Name: Glass Ionomer Cements

Product Code: EMA

Classification: Class II

Classification Name: Cement, Dental

Regulation Number: 872.3275

Review Panel: Dental

PREDICATE DEVICES:

Nova Glass Cements (Nova Glass L, Nova Glass F, Nova Glass LC, Nova Glass BF, Nova Glass L Plus) is substantially equivalent to the following marketed product:

COMPANY	DEVICE	510(k) NUMBER	PRODUCT CODE
Silmet Ltd.	ProGlass Cements (ProGlass One, ProGlass Two, ProGlass Two LC, ProGlass Nine, ProGlass Plus, ProGlass Silver)	K101869 (Primary Predicate)	EMA

INDICATION FOR USE:

Nova Glass L	-Cementation of all types of metal, Porcelain fused to metal, resin crowns, inlays, onlays & bridges -Cementation of orthodontic bands -Cementation of stainless steel crowns or orthodontic appliances retained with stainless steel crowns -Base/liner
Nova Glass F	-Class III, V and limited class I cavities -Restoration of primary teeth -Core Build Up
Nova Glass LC	-Class III and V restorations -Restoration of Cervical erosions and root surface caries -Core Build Up -Base/Liner
Nova Glass BF	-Class I & II cavities -Deciduous teeth: final restorative for Class I, II and V -Long term restorative in non-load bearing areas of Class I, II and V -Intermediate restorative & sandwich material for heavy stress bearing -Core build up material
Nova Glass L Plus	-Metal-based restorations -Ceramic inlays -Reinforced ceramic crowns and bridges -All kind of acrylic/resin crowns, inlays, onlays and bridges

DEVICE DESCRIPTION:

- Nova Glass Cements are devices intended to serve as a temporary tooth filling or as a base cement to affix a temporary tooth filling.
- Nova Glass Cements are based on the reaction of silicate glass powder and polyalkeonic acid. (acid-base reaction)
- Nova Glass Cements are formulated to provide a powder and a liquid portion. In use the two are combined and a chemical reaction takes place to provide set cement.

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 Glass Cements (Nova Glass L, Nova Glass F, Nova Glass LC, Nova Glass BF, Nova Glass L Plus) and the predicates.

Table 1

DESCRIPTIVE INFORMATION	NEW DEVICE NOVA GLASS CEMENTS (K210473)	PREDICATE DEVICE ProGlass Cements (K101869)
INDICATIONS FOR USE		
	Nova Glass L -Cementation of all types of metal, Porcelain fused to metal, resin crowns, inlays, onlays & bridges -Cementation of orthodontic bands -Cementation of stainless steel crowns or orthodontic appliances retained with stainless steel crowns -Base/liner	ProGlass One -Cementation of all types of metal, Porcelain fused to metal, resin crowns, inlays, onlays & bridges -Cementation of orthodontic bands -Cementation of stainless steel crowns or orthodontic appliances retained with stainless steel crowns -Base/liner
	Nova Glass F -Class III, V and limited class I cavities -Restoration of primary teeth -Core Build Up	ProGlass Two -Class III, V and limited class I cavities -Restoration of primary teeth -Core Build Up
	Nova Glass LC -Class III and V restorations -Restoration of Cervical erosions and root surface caries -Core Build Up -Base/Liner	ProGlass Two LC -Class III and V restorations -Restoration of Cervical erosions and root surface caries -Core Build Up -Base/Liner
	Nova Glass BF -Class I & II cavities -Decidious teeth: final restorative for Class I, II and V -Long term restorative in non-load bearing areas of Class I, II and V -Intermediate restorative & sandwich material for heavy stress bearing -Core build up material	ProGlass Nine -Class I & II cavities -Decidious teeth: final restorative for Class I, II and V -Long term restorative in non-load bearing areas of Class I, II and V -Intermediate restorative & sandwich material for heavy stress bearing -Core build up material
	Nova Glass L Plus -Metal-based restorations -Ceramic inlays -Reinforced ceramic crowns and bridges -All kind of acrylic/resin crowns, inlays, onlays and bridges	ProGlass Plus -Metal-based restorations -Ceramic inlays -Reinforced ceramic crowns and bridges -All kind of acrylic/resin crowns, inlays, onlays and bridges
FUNCTION		
	Nova Glass L Luting Cement	ProGlass One Luting Cement
	Nova Glass F Restorative	ProGlass Two Restorative
	Nova Glass LC Reinforced Restorative Base/Liner	ProGlass Two LC Reinforced Restorative Base/Liner

	Nova Glass BF Restorative Base/Liner	ProGlass Nine Restorative Base/Liner			
	Nova Glass L Plus Luting Cement	ProGlass Plus Luting Cement			
COMPOSITION					
	Nova Glass L Powder: Alumino-silicate glass, polyacrylic acid Liquid: Distilled water, polyacrylic acid	ProGlass One Powder: Alumino-silicate glass, polyacrylic acid Liquid: Distilled water, polyacrylic acid			
	Nova Glass F Powder: Alumino-silicate glass, polyacrylic acid Liquid: Distilled water, polyacrylic acid	ProGlass Two Powder: Alumino-silicate glass, polyacrylic acid Liquid: Distilled water, polyacrylic acid			
	Nova Glass LC Powder: Alumino-silicate glass Liquid: Distilled water, polyacrylic acid, 2-hydroxyethyl methacrylate (HEMA), 2,2,4, Trimethyl hexamethylene dicarbonate (TMHMD)	ProGlass Two LC Powder: Alumino-silicate glass Liquid: Distilled water, polyacrylic acid, 2-hydroxyethyl methacrylate (HEMA), 2,2,4, Trimethyl hexamethylene dicarbonate (TMHMD)			
	Nova Glass BF Powder: Alumino-silicate glass, polyacrylic acid Liquid: Polyacrylic acid, tartaric acid, distilled water	ProGlass Nine Powder: Alumino-silicate glass, polyacrylic acid Liquid: Polyacrylic acid, tartaric acid, distilled water			
	Nova Glass L Plus Powder: Alumino-silicate glass Liquid: Distilled water, polyacrylic acid, 2-Hydroxyethylmethacrylate, Urethanedimethacrylate	ProGlass Plus Powder: Alumino-silicate glass Liquid: Distilled water, polyacrylic acid, 2-Hydroxyethylmethacrylate, Urethanedimethacrylate			
PHYSICAL PROPERTIES					
	Nova Glass L & ProGlass One	Nova Glass F & ProGlass Two	Nova Glass LC & ProGlass Two LC	Nova Glass BF & ProGlass Nine	Nova Glass L Plus & ProGlass Plus
Powder/Liquid	2.4 / 1.0	3.5 / 1.0	2.3 / 1.0	4.1 / 1.0	1.5 / 1.0
Mixing Time (sec)	30"	30"	30"	30"	30"
Working Time (min. sec)	2'30"- 3"	1'30" – 2'	3'	2'30"	3'
Setting Time (min. sec)	3'10" -	3' 10" – 3'	3'	3' 30"	3'
Light Cure (sec)			20"		

Similarities

- Nova Glass Cements; 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 as safety and as effectiveness of Nova Glass Cements for the intended use.

Differences

- There is no silver-containing version of Nova Glass Cements.

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 Glass Cements (Nova Glass L, Nova Glass F). The biocompatibility data for Nova Glass Cements (Nova Glass L, Nova Glass F) are given in the table below.

Test Name	Report Number	Result
<i>Cytotoxicity</i>	<i>BU-2021/07-ST</i>	<i>It does not cause cytotoxicity.</i>
<i>Acute Systemic Toxicity</i>	<i>2018-IVV-AST-105-213</i>	<i>It does not cause acute systemic toxicity.</i>
<i>Genotoxicity (OECD 487)</i>	<i>2019-.09.170</i>	<i>It has no genotoxic potential.</i>
<i>Genotoxicity (OECD 471)</i>	<i>2020.07.226</i>	<i>It does not have mutagenic potential.</i>
<i>Sensitization</i>	<i>2017-IVV-SEN-112-160</i>	<i>It does not cause sensitization.</i>
<i>Subacute Systemic Toxicity</i>	<i>2018-IVV-SST-104-209</i>	<i>It does not have a subacute systemic effect.</i>
<i>Irritation</i>	<i>2017-IVV-IRT-112-119</i>	<i>It does not cause irritation.</i>
<i>Implantation</i>	<i>2019.12.256</i>	<i>It does not cause implantation.</i>

Material-Mediated Pyrogenicity;

Nova Glass L and Nova Glass F components are found in the legally marketed devices:

The material, design and use concept is similar.

We believe that the prior use of these components in legally marketed device and the performance data and results support the substantial equivalence of Nova Glass Cements for the intended use.

Chronic Toxicity;

Nova Glass L and Nova Glass F components are found in the legally marketed devices:

The material, design and use concept is similar.

We believe that the prior use of these components in legally marketed device and the performance data and results support the substantial equivalence of Nova Glass Cements for the intended use.

Carcinogenicity;

Nova Glass L and Nova Glass F components are found in the legally marketed devices:

The material, design and use concept is similar.

We believe that the prior use of these components in legally marketed device and the performance data and results support the substantial equivalence of Nova Glass Cements for the intended use.

Nova Glass Cements (Nova Glass LC, Nova Glass BF, Nova Glass L Plus)

Nova Glass Cements (Nova Glass LC, Nova Glass BF, Nova Glass L Plus) components are found in the legally marketed devices:

The material, design and use concept is similar.

Biocompatibility testing has not been performed for our Nova Glass LC, Nova Glass BF, Nova Glass L Plus products.

We believe that the prior use of these components in legally marketed device and the performance data and results support the substantial equivalence of Nova Glass Cements for the intended use.

The prior use of all the components in the legally marketed devices supports our decision that additional testing for cytotoxicity and mutagenicity as well as additional bio-compatibility studies with the final formulation are not necessary.

Physical Testing:

In-vitro bench tests were performed on the Nova Glass Cements (Nova Glass L, Nova Glass F, Nova Glass LC, Nova Glass BF, Nova Glass L Plus) according to the requirements in ISO 9917-1:2007 (Dentistry - Water-based cements - Part 1: Powder/liquid acid-base cements).

Bench tests included in support of the substantial equivalence of Nova Glass Cements (Nova Glass L, Nova Glass F, Nova Glass LC, Nova Glass BF, Nova Glass L Plus) are:

- Film Thickness
- Setting Time
- Compressive Strength
- Acid Erosion
- Opacity
- Acid Soluble Pb Content
- Mixing Time
- Working Time

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 DİŞ MALZEMELERİ SANAYİ VE TİCARET A.S. concludes that the Nova Glass Cements (Nova Glass L, Nova Glass F, Nova Glass LC, Nova Glass BF, Nova Glass L Plus) are as safe and as 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.