August 9, 2022

Imicryl Dis Malzemeleri Sanayi Ve Ticaret As
Husamettin Sonmez
General Manager
Fetih Mahallesi Mahir Sokak No:5/201 Karatay
Konya, 42030
Turkey

Re: K220077
Trade/Device Name: IMICRYL Composite, Composite Flow Materials
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF, EBC, EJK
Dated: July 5, 2022
Received: July 11, 2022

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 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220077

Device Name
IMICRYL Composite, Composite Flow Materials

Indications for Use *(Describe)*
IMICRYL COMPOSITE (Nova Compo C, Nova Compo MHC, Nova Compo HS, Balo, Swarpe)
- Direct anterior & posterior restorations
- Core Build Ups
- Splinting

IMICRYL COMPOSITE FLOW (Nova Compo HF, Othocompo, Luxera, Maritza)
- Class III, V & smaller Class IV restorations
- Base/liner in Class I & Class II restorations
- Repair resin, porcelain & acrylic temporary materials
- Pit & fissure sealant
- Undercut blockout
- Restoration of minimally invasive cavity preparations

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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K220077

510(k) Summary

IMICRYL Composite, Composite Flow Materials

*The IMICRYL family of **composite materials**: includes the brand names Nova Compo C, Nova Compo MHC, Nova Compo HS, Balo and Swarpe.*

*The IMICRYL family of **composite flow materials**: includes the brand names Nova Compo HF, Othocompo, Luxera, Maritza*

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Date of Summary Preparation: November 30, 2021

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

Phone Number: 0090 444 71 30

Fax Number: 0090 332 355 76 19

Contact Person: Husamettin SONMEZ

Phone: 0090 444 71 30 ext: 120

E-mail: kaliteguvence@imicryl.com

Secondary Contact Person: Muhammed Hulusi SONMEZ

Phone: 0090 444 71 30 ext: 123

E-mail: hsonmez@imicryl.com.tr

DEVICE INFORMATION:

Trade Name: IMICRYL Composite, Composite Flow Materials

Common Name: Composite Materials

Primary Product Code: EBF

Secondary Product Code: EJK, EBC

Classification: Class II

Classification Name: Tooth shade resin, material 21 CFR 872.3690

Regulation Number: 21 CFR 872.3690

Review Panel: Dental

PREDICATE DEVICES:

IMICRYL Composite, Composite Flow Materials is substantially equivalent to the following marketed product:

COMPANY	DEVICE	510(k) NUMBER	PRODUCT CODE
Silmet Ltd.	ProFil Composites (ProFil, ProFil Flow)	K103190	EBF

INDICATION FOR USE:

IMICRYL COMPOSITE (Nova Compo C, Nova Compo MHC, Nova Compo HS, Balo, Swarpe)

- Direct anterior & posterior restorations
- Core Build Ups
- Splinting

IMICRYL COMPOSITE FLOW (Nova Compo HF, Othocompo, Luxera, Maritza)

- Class III, V & smaller Class IV restorations
- Base/liner in Class I & Class II restorations
- Repair resin, porcelain & acrylic temporary materials
- Pit & fissure sealant
- Undercut blockout
- Restoration of minimally invasive cavity preparations

DEVICE DESCRIPTION:

IMICRYL Composite Materials include the brands Nova Compo C, Nova Compo MHC, Nova Compo HS, Balo and Swarpe. IMICRYL Composite Materials; It is a light-cured, radiopaque, universal hybrid composite suitable for use in the anterior and posterior regions. It is packaged in a black syringe to protect it from light.

IMICRYL Flow Composite materials include the Nova Compo HF, Othocompo, Luxera and Maritza brands. IMICRYL Flow Composite materials; It is a light-cured hybrid radiopaque composite with a fluid consistency. Composite materials are a mixture of organic resin and inorganic filler. The resin matrix contains Bis-GMA and TEGDMA is added to decrease the viscosity.

There are differences in viscosity between composites and flowable composites.

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 IMICRYL Composite, Composite Flow Materials and the predicates.

Table 1: Comparison with Predicate Device

DESCRIPTIVE INFORMATION	NEW DEVICE IMICRYL Composite, Composite Flow Materials (K220077)	PREDICATE DEVICE ProFil Composites (ProFil, ProFil Flow), [K103190]	REMARK
INDICATIONS FOR USE			
	IMICRYL COMPOSITE (Nova Compo C, Nova Compo MHC, Nova Compo HS, Balo, Swarpe) • Direct anterior & posterior restorations • Core Build Ups • Splinting IMICRYL COMPOSITE FLOW (Nova Compo HF, Othocompo, Luxera, Maritza) • Class III, V & smaller Class IV restorations • Base/liner in Class I & Class II restorations • Repair resin, porcelain & acrylic temporary materials • Pit & fissure sealant • Undercut blockout • Restoration of minimally invasive cavity preparations	ProFil • Direct anterior & posterior restorations • Core Build Ups • Splinting ProFil Flow • Class III, V & smaller Class IV restorations • Base/liner in Class I & Class II restorations • Repair resin, porcelain & acrylic temporary materials • Pit & fissure sealant • Undercut blockout • Restoration of minimally invasive cavity preparations	The indications for use of the new device and the equivalent device are the same.

Similarities

- IMICRYL Composite, Composite Flow Materials 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 IMICRYL Composite, Composite Flow Materials for the intended use.

Differences

- There is no difference.

TECHNOLOGICAL PROPERTIES

Technological property	NEW DEVICE IMICRYL Composite, Composite Flow Materials (K220077)	PREDICATE DEVICE ProFil Composites (ProFil, ProFil Flow), [K103190]
Camphorquinone/amine photoinitiator system	✓	✓
Methacrylate-based resin matrix	✓	✓
Silane treated fillers	✓	✓
Bonded with a permanent dental adhesive	✓	✓
When irradiated by light, the methacrylate functionalities of the resins and surface treated fillers undergo, in conjunction with the photoinitiator system, I light induced polymerization to form a hard composite that is bonded to the tooth structure with a permanent dental adhesive	✓	✓

NON-CLINICAL BENCH TESTING:

IMICRYL COMPOSITE AND PROFIL COMPOSITE TEST RESULTS

Sample Name	Compressive Strength (MPa)	Flexural Strength (MPa)	Surface Hardness (MHV)	Water Sorption (µg/mm^3)	Water Solubility (µg/mm^3)
IMICRYL Composite, Materials (Lot No: 17125)	420 MPa	167 MPa	265 MHV	16.8 µg/mm^3	0.3 µg/mm^3
ProFil Composite	440 MPa	187 MPa	285 MHV	18.4 µg/mm^3	0.5 µg/mm^3

Sample Name	Polymerization Shrinkage	Diametral Tensile Strength	Flexural Modulus	Radiopacity	Depth of Cure
IMICRYL Composite (Lot No: 17125)	1.45 %	31 MPa	126.87 MPa	6 mm of Al	2.5 mm
ProFil Composite	1.57 %	30 MPa	130 MPa	6.87 mm of Al	2.8 mm

Sample Name	Elastic Modulus	Intensity for Curing	Wavelength for Curing	Filler Particle Size Distribution
IMICRYL Composite (Lot No: 17125)	16.8 GPa	1200 mW/cm^2 - 10 sec. 500 mW/cm^2 – 20 sec.	470 nm	0.7 µm
ProFil Composite	17.1 GPa	1200 mW/cm^2 - 10 sec. 500 mW/cm^2 – 20 sec.	470 nm	0.7 µm

Sample Name	Working Time	Setting Time	Curing Time
IMICRYL Composite (Lot No: 17125)	38 second	4 minute	20 second
ProFil Composite	35 second	4 minute 10 second	20 second

IMICRYL COMPOSITE FLOW AND PROFIL COMPOSITE FLOW TEST RESULTS

Sample Name	Compressive Strength (MPa)	Flexural Strength (MPa)	Surface Hardness (MHV)	Water Sorption (µg/mm^3)	Water Solubility (µg/mm^3)
IMICRYL Composite Flow (Lot No: 17126)	380 MPa	165 MPa	265 MHV	16.8 µg/mm^3	0.3 µg/mm^3
ProFil Composite Flow	370 MPa	160 MPa	285 MHV	18.4 µg/mm^3	0.5 µg/mm^3

Sample Name	Polymerization Shrinkage	Diametral Tensile Strength	Flexural Modulus	Radiopacity	Depth of Cure
IMICRYL Composite Flow (Lot No: 17126)	2.2 %	68 MPa	126.87 MPa	3.5 mm of Al	3.8 mm
ProFil Composite Flow	2 %	65 MPa	130 MPa	3 mm of Al	3 mm

Sample Name	Elastic Modulus	Intensity for Curing	Wavelength for Curing	Filler Particle Size Distribution
IMICRYL Composite Flow (Lot No: 17126)	16.8 GPa	1200 mW/cm^2 - 10 sec 500 mW/cm^2 – 20 sec	470 nm	0.7 µm
ProFil Composite Flow	17.1 GPa	1200 mW/cm^2 - 10 sec 500 mW/cm^2 – 20 sec	470 nm	0.7 µm

Sample Name	Working Time	Setting Time	Curing Time
IMICRYL Composite Flow (Lot No: 17126)	38 second	4 minute	20 second
ProFil Composite Flow	35 second	4 minute 10 second	20 second

NON-CLINICAL PERFORMANCE TESTING:

Biocompatibility Testing:

Cytotoxicity	The device has not cytotoxic potential.
Sensitization	The device does not cause hypersensitive skin reaction.
Intradermal Reactivity	The device does not cause intradermal irritation.
Acute Systemic Toxicity	The device has no acute systemic toxic effect.
Subacute Systemic Toxicity (non-polar)	The device does not have a subacute systemic toxic effect.
Subacute Systemic Toxicity (polar)	The device does not have a subacute systemic toxic effect.
Genotoxicity (OECD 471)	The device has no mutagenic potential.
Genotoxicity (OECD 487)	The device has no genotoxic potential.
Implantation	Irritant effect was not found.

Physical Testing:

In-vitro bench tests were performed on the IMICRYL Composite, Composite Flow Materials according to the requirements in ISO 4049 Dentistry — Polymer-based restorative materials and ISO 17304 Dentistry — Polymerization Shrinkage: Method For Determination of Polymerization Shrinkage of Polymer-Based Restorative Materials.

Bench tests included in support of the substantial equivalence of IMICRYL Composite, Composite Flow are:

- Compressive Strength
- Flexural Strength
- Surface Hardness
- Water Sorption and Solubility
- Polymerization Shrinkage
- Diametral Tensile Strength
- Flexural Modulus
- Radiopacity
- Depth of Cure

CONCLUSION

In accordance with 21 C.F.R part 807 and FDA' s "Guidance for the preparation of Premarket Notifications for Dental Composites" and based on the information provided in this premarket notification, IMICRYL AS. concludes that IMICRYL Composite, Composite Flow Materials are safe and effective and substantially equivalent to the predicate devices described herein.