February 11, 2022

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

Re: K213890
Trade/Device Name: IMICRYL Impression Materials
Regulation Number: 21 CFR 872.3660
Regulation Name: Impression Material
Regulatory Class: Class II
Product Code: ELW
Dated: December 6, 2021
Received: December 13, 2021

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 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)*
K213890

Device Name
IMICRYL Impression Materials

Indications for Use *(Describe)*
PUTTY SOFT is to be used as preliminary materials for:
-Two-step Putty-wash impression technique
-One-step Putty-wash impression technique
HEAVY BODY materials for:
-One-step impression technique (simultaneous technique) using single or dual viscosities
-Two-step impression technique using dual viscosities
-Functional impression
MEDIUM/MONOPHASE/REGULAR BODY tray or syringeable impression material for:
-Taking impressions over fixed/removable restorations and implants (i.e., transferring impression posts and bridge components)
-Functional impressions
-Fabricating crown and bridgework or inlays
-Fabricating full or partial dentures
-Reline impressions
-Use in the simultaneous mixing technique as well as the putty-wash and triple tray techniques
-Transferring root posts when fabricating posts and cores indirectly
LIGHT BODY is to be used as syringeable impression materials for:
-Two-step putty-wash impression technique
-One-step putty-wash impression technique
-Two-step impression technique using dual viscosities
-Reline impressions
-Fabricating full or partial dentures
EXTRA LIGHT BODY is to be used as syringeable impression materials for:
-Two-step putty-wash impression technique
-One-step putty-wash impression technique
-Two-step impression technique using dual viscosities
-Reline impressions
-Fabricating full or partial dentures
BITE REGISTRATION is used for impression as below.
-Taking occlusal surfaces
-Confirming occlusal surfaces
-Recording after putting the articulator

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 - K213890

IMICRYL Impression Materials

The IMICRYL family of silicone impression materials: includes the brand names SPIRIAS, NICETY, REFLECT and PE Sil.

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 542 372 27 23

E-mail: hsonmez@imicryl.com.tr

DEVICE INFORMATION:

Trade Name: IMICRYL Impression Materials

Common Name: Impression Material

Product Code: ELW

Classification: Class II

Classification Name: Material, Impression

Regulation Number: 21 CFR 872.3660

Review Panel: Dental

PREDICATE DEVICES:

IMICRYL Impression Materials is substantially equivalent to the following marketed product:

COMPANY	DEVICE	510(k) NUMBER	PRODUCT CODE
Osstem Implant Co., Ltd.	HySil Impression Materials	K170736	ELW

INDICATION FOR USE:

SPIRIAS, NICETY, REFLECT and PE Sil **Putty Soft** is to be used as preliminary materials for:
Two-step Putty-wash impression technique
One-step Putty-wash impression technique

SPIRIAS, NICETY, REFLECT and PE Sil **Heavy Bodied** materials for:
One-step impression technique (simultaneous technique) using single or dual viscosities
Two-step impression technique using dual viscosities
Functional impression

SPIRIAS, NICETY, REFLECT and PE Sil **Medium/Monophase/Regular Bodies** tray or syringeable impression material for:
• Taking impressions over fixed/removable restorations and implants (i.e., transferring impression posts and bridge components)
• Functional impressions
• Fabricating crown and bridgework or inlays
• Fabricating full or partial dentures
• Reline impressions
• Use in the simultaneous mixing technique as well as the putty-wash and triple tray techniques
• Transferring root posts when fabricating posts and cores indirectly

SPIRIAS, NICETY, REFLECT and PE Sil **Light Body** is to be used as syringeable impression materials for:
Two-step putty-wash impression technique
One-step putty-wash impression technique
Two-step impression technique using dual viscosities
Reline impressions
Fabricating full or partial dentures

SPIRIAS, NICETY, REFLECT and PE Sil **Extra Light Body** is to be used as syringeable impression materials for:
Two-step putty-wash impression technique
One-step putty-wash impression technique
Two-step impression technique using dual viscosities
Reline impressions
Fabricating full or partial dentures

SPIRIAS, NICETY, REFLECT and PE Sil **Bite Registration** is used for impression as below.
• Taking occlusal surfaces
• Confirming occlusal surfaces
• Recording after putting the articulator

DEVICE DESCRIPTION:

The IMICRYL family of silicone impression materials: includes the brand names SPIRIAS, NICETY, REFLECT and PE Sil. It is used by dentists to obtain anatomical data of the patient's mouth and then to obtain a useful plaster cast to diagnose problems, identify necessary interventions and/or check their effectiveness. They are elastomeric materials with hydrophilic properties, high tear strength, dimensional accuracy and resistance to permanent deformation, cured by addition reaction.

The IMICRYL family of silicone impression materials consists of six different viscosities (putty soft, heavy body, medium/monophase/regular body, light body, extra light body, bite registration) for various application systems. Putty Soft consists of 1:1 250 and 1:1 300 mL jars, other consistencies 1:1 50 mL syringes. Although the consistency and composition of medium, monophase and regular body products, which have type 2 consistency, are exactly the same, they are offered for sale under three different names.

IMICRYL impression materials meet the requirements of ISO 4823:2021 Dentistry- Elastomeric impression and bite registration materials standard.

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 Impression Materials and the predicates.

Table 1: Comparison with Predicate Device

DESCRIPTIVE INFORMATION	NEW DEVICE IMICRYL Impression Materials (K213890)	PREDICATE DEVICE HySil Impression Materials (K170736)	REMARK
INDICATIONS FOR USE			
	Putty Soft SPIRIAS, NICETY, REFLECT and PE Sil Putty Soft is to be used as preliminary materials for: Two-step Putty-wash impression technique One-step Putty-wash impression technique	**Putty** HySil Putty is to be used as preliminary materials for: Two-step Putty-wash impression technique One-step Putty-wash impression technique	Same Indications for Use
	Heavy Body SPIRIAS, NICETY, REFLECT and PE Sil Heavy Bodied materials for: One-step impression technique (simultaneous technique) using single or dual viscosities Two-step impression technique using dual viscosities Functional impressions	**Heavy Body** HySil Heavy is to be used as heavy-bodied materials for: One-step impression technique (simultaneous technique) using single or dual viscosities Two-step impression technique using dual viscosities Functional impressions	
	Medium/Monophase/Regular Body SPIRIAS, NICETY, REFLECT and PE Sil Medium/Monophase/Regular Bodies tray or syringeable impression material for: _ Taking impressions over fixed/removable restorations and implants (i.e., transferring impression posts and bridge components) _ Functional impressions _ Fabricating crown and bridgework or inlays _ Fabricating full or partial dentures _ Reline impressions _ Use in the simultaneous mixing technique as well as the putty-wash and triple tray techniques _ Transferring root posts when fabricating posts and cores indirectly	**Medium Body** HySil Mono is to be used as a medium-bodied tray or syringeable impression material for: _ Taking impressions over fixed/removable restorations and implants (i.e., transferring impression posts and bridge components) _ Functional impressions _ Fabricating crown and bridgework or inlays _ Fabricating full or partial dentures _ Reline impressions _ Use in the simultaneous mixing technique as well as the putty-wash and triple tray techniques _ Transferring root posts when fabricating posts and cores indirectly	
	Light Body SPIRIAS, NICETY, REFLECT and PE Sil Light Body is to be used as syringeable impression materials for: Two-step putty-wash impression technique	**Light Body** HySil Light is to be used as syringeable impression materials for: Two-step putty-wash impression technique	

	One-step putty-wash impression technique Two-step impression technique using dual viscosities Reline impressions • Fabricating full or partial dentures	One-step putty-wash impression technique Two-step impression technique using dual viscosities Reline impressions • Fabricating full or partial dentures	
	Extra Light Body SPIRIAS, NICETY, REFLECT and PE Sil Extra Light Body is to be used as syringeable impression materials for: Two-step putty-wash impression technique One-step putty-wash impression technique Two-step impression technique using dual viscosities Reline impressions Fabricating full or partial dentures	**Extra Light Body** HySil Extra Light is to be used as syringeable impression materials for: Two-step putty-wash impression technique One-step putty-wash impression technique Two-step impression technique using dual viscosities Reline impressions Fabricating full or partial dentures	
	Bite Registration SPIRIAS, NICETY, REFLECT and PE Sil Bite Registration is used for impression as below. Taking occlusal surfaces Confirming occlusal surfaces Recording after putting the articulator	**Bite** HySil Bite is used for impression as below. Taking occlusal surfaces Confirming occlusal surfaces Recording after putting the articulator	
COMPOSITION			
	Putty Soft, Heavy Body, Medium/Monophase/Regular Body, Light Body, Extra Light Body, Bite Registration Vinylpolysiloxane	**Putty, Heavy, Mono, Light, Extra-Light, Bite** Vinylpolysiloxane	Composed with same affiliated material, but ratios of each component in use are slightly different.

PHYSICAL PROPERTIES

	Putty Soft		**Heavy Body**		**Medium / Monophase / Regular Body**		**Light Body**		**Extra Light**	
	New Device	**Predicate Device**	**New Device**	**Predicate Device**	**New Device**	**Predicate Device**	**New Device**	**Predicate Device**	**New Device**	**Predicate Device**
Type	**Type 0**	**Type 0**	**Type 1**	**Type 1**	**Type 2**	**Type 2**	**Type 3**	**Type 3**	**Type 3**	**Type 3**
Consistency	28,40 mm	31,27 mm	30,18 mm	28,47 mm	34,35 mm	35,65 mm	36,67 mm	45,60 mm	43,42 mm	44,61 mm
Working Time	90 sec	-	90 sec	2,022 min	90 sec	2,612 min	90 sec	2,850 min	90 sec	3,6 min
Mixing Time	30 sec	38 sec	Auto (30 sec)	Pass	Auto (30 sec)	Pass	Auto (30 sec)	Pass	Auto (30 sec)	Pass
Detail Reproduction	50µm	Pass	20µm	Pass	20µm	Pass	20µm	Pass	20µm	Pass

Compatibility with gypsum	50µm	Pass	20µm	Pass	20µm	Pass	20µm	Pass	20µm	Pass
Linear Dimensional change	0,01%	0,031 %	0,01%	0,02 %	0,02%	0,02 %	0,02%	0,03 %	0,02%	0,027 %
Elastic Recovery	99,00%	99,8 %	99,60%	98,80 %	99,99%	98,60 %	99,99%	98,70 %	99,99%	99,5 %
Strain-in-Compression	1,6%	1,6 %	2,30%	2,30 %	3,68%	3,00 %	3,38 %	2,30 %	3,18%	2,6 %
PHYSICAL PROPERTIES										

	Bite Registration	
	New Device	**Predicate Device**
Type	**Type B**	**Type B**
Mixing Time	30 sec	Pass
Working Time	90 sec	Pass
Time in Mouth (minimum)	3 min	1 min. 30 sec.
Linear Dimensional change	0,02%	-0,16 %
Compression set	0,06mm	Pass
Hardness	55 HD	50 HD

Similarities

- IMICRYL Impression 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 Impression Materials for the intended use.

NON-CLINICAL PERFORMANCE TESTING:

Biocompatibility Testing:

Cytotoxicity, irritation and sensitization tests of the device were performed. The device is biocompatible.

Physical Testing:

In-vitro bench tests were performed on the IMICRYL Impression Materials according to the requirements in ISO 4823:2021 Dentistry-Elastomeric impression and bite registration materials.

Bench tests included in support of the substantial equivalence of IMICRYL Impression Materials are:

- Consistency
- Working Time
- Mixing Time
- Detail Reproduction
- Compatibility with Gypsum
- Linear Dimensional Change
- Elastic Recovery
- Strain-in-Compression
- Time in Mouth
- Compression Set
- Hardness

CONCLUSION

In accordance with the Federal Food, Drug and Cosmetic Act and 21 CFR Part 872.3660, and based on the information provided in this pre-market notification, IMICRYL DIS MALZEMELERI SANAYI VE TICARET A.S. concludes that the IMICRYL Impression Materials 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.