November 25, 2025

LuxCreo Inc.
Tao Feng
VP of Legal
350 W. Ontario Street, Suite 700
Chicago, Illinois 60654

Re: K253365
Trade/Device Name: LuxCreo Flexible Partial Denture Resin
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture Relining, Repairing, Or Rebasing Resin
Regulatory Class: Class II
Product Code: EBI
Dated: September 29, 2025
Received: September 30, 2025

Dear Tao Feng:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

Michael E. Adjodha, MChE, RAC, CQIA
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)*
K253365

Device Name
LuxCreo Flexible Partial Denture Resin

Indications for Use *(Describe)*
LuxCreo Flexible Partial Denture Resin is a liquid light-curing resin indicated for the fabrication and repair of partial denture bases. It is intended for use by dental professionals in dental and orthodontic laboratories and clinics.

LuxCreo Flexible Partial Denture Resin is intended for the additive manufacturing of removable partial denture bases, including denture bases for interim and transitional dentures, for the replacement of one or more missing teeth. The device is supported by remaining natural dentition and oral tissues. Partial dentures manufactured using this resin may be used permanently as a total removable replacement or temporarily while the patient is preparing for permanent implant.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Section 20-2 510(k) Summary

1. 510(k) Number
TBD

2. Date Prepared
November 25th, 2025

3. Submitter
LuxCreo Inc.
350 W. Ontario Street Suite 700, Chicago, IL 60654
Registration Number: 3016237718
FEI Number: 3016237718
Tel:+1 650-336-0888

4. Contact Person
Tao Feng
Title: VP of Legal
Telephone Number: 732-301-4246
Email: tao.feng@luxcreo.com

5. Device
5.1 Device information
Device Name: LuxCreo Flexible Partial Denture Resin
Model: Clear
Device Classification Name: Resin, Denture, Relining, Repairing, Rebasing
Regulation Description: Denture relining, repairing, or rebasing resin
Regulation Number: 21 CFR 872.3760
Device Class: Class II
Product Code: EBI
Review Panel: Dental

5.2 Use of Device

Question	Yes	No
Is the device intended for prescription use (21 CFR 801 Subpart D)?	√	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		√

Question	Yes	No
Does the device contain components derived from a tissue or other biologic source?		√
Is the device provided sterile?		√
Is the device intended for single use?	√	
Is the device a reprocessed single use device?		√
If yes, does this device type require reprocessed validation data?		√
Does the device contain a drug?		√
Does the device contain a biologic?		√
Does the device use software?		√
Does the submission include clinical information?		√
Is the device implanted?		√

5.3 Design

LuxCreo Flexible Partial Denture Resin is a liquid light-curing resin indicated for the fabrication and repair of partial denture bases. To accomplish this three-dimensional fabrication, a 3D printer, based on a 3D stereolithographic drawing, prints the pre-determined shape of each dental appliance. 3D Printing uses specialty liquid resins, which when combined with UV (385~405nm) and/or thermal treatment, allows the fabricated part to achieve mechanical properties similar to thermoplastics and excellent biological safety results.

LuxCreo Flexible Partial Denture Resin is designed to be used in a system with components of scanner, design fabrication software, validated 3D Printer, cleaning system, and post-curing unit. These components are used together during the additive manufacturing of partial denture bases.

Partial denture bases are constructed using LuxCreo Flexible Partial Denture Resin in accordance to the following steps:

1) Design: Patient's bite and dentition is digitally reproduced via intra-oral scan. The quality of the scan impacts the quality and fitment of the resulting device, and is the responsibility of an appropriately trained and qualified practitioner. A dental design service or dental CAD software (e.g. Exocad PartialCAD and LuxDesign) can be used to design dental models in according to treatment plan. The dental model files are imported into dental CAD software (e.g. Exocad PartialCAD and LuxDesign) to generate flexible partial denture base model files.

2) Printing: The flexible partial denture base model files are imported into a slicing software (e.g. LuxFlow) to render the CAD model 3D printable. The CAD model is then sent to an appropriate 3D Printer (e.g. a LuxCreo printer such as iLux Pro Dental and fastprint.io). The 3D printer constructs the partial denture bases out of LuxCreo Flexible Partial Denture Resin.

3) Post-processing: After printing, the printed partial denture bases are subjected to a post-processing treatment that includes cleaning excess resin from the printed part, subjecting the part to additional UV and/or thermal treatment, and finishing the part via support removal and/or any buffing or polishing steps that a dental health professional deems appropriate for aesthetic and functional purposes.

Dental professionals can then attach the teeth to the finished flexible denture base using FDA-cleared dental materials, such as approved teeth and adhesive, to construct the partial denture.

5.4 Labeling

We provide the labeling for the subject device in submission, including the following elements:

- Manufacturer Information
- Intended Use
- Instructions for Clinician Use
- Warnings
- Product feature and technical parameter
- Cleaning instruction

5.5 Sterilization

There is no sterilization in this 510(k) submission.

5.6 Software

N/A

6. Intended Use

6.1 Intended Use

LuxCreo Flexible Partial Denture Resin is a liquid light-curing resin indicated for the fabrication and repair of partial denture bases. It is intended for use by dental professionals in dental and orthodontic laboratories and clinics.

6.2 Indications

LuxCreo Flexible Partial Denture Resin is intended for the additive manufacturing of removable partial denture bases, including denture bases for interim and transitional dentures, for the replacement of one or more missing teeth. The device is supported by remaining natural dentition and oral tissues. Partial

dentures manufactured using this resin may be used permanently as a total removable replacement or temporarily while the patient is preparing for permanent implant.

7. Predicate and Reference Device

7.1 Primary Predicate Device:

Primary Predicate Device Name: Apex Flex
Device Classification Name: Resin, Denture, Relining, Repairing, Rebasing
Regulation Description: Denture relining, repairing, or rebasing resin.
Regulation Number: 21 CFR 872.3760
Device Class: Class II
Product Code: EBI
510(k) Number: K250617
510(k) Submitter: SprintRay Inc.
Review Panel: Dental

7.2 Secondary Predicate Device:

Primary Predicate Device Name: FP3D
Device Classification Name: Resin, Denture, Relining, Repairing, Rebasing
Regulation Description: Denture relining, repairing, or rebasing resin.
Regulation Number: 21 CFR 872.3760
Device Class: Class II
Product Code: EBI
510(k) Number: K250489
510(k) Submitter: Keystone Industries
Review Panel: Dental

7.3 Reference Device:

Reference Device Name: LuxCreo Clear Aligner System
Device Classification Name: Aligner, Sequential
Regulation Description: Orthodontic plastic bracket.
Regulation Number: 21 CFR 872.5470
Device Class: Class II
Product Code: NXC
510(k) Number: K250343
510(k) Submitter: LuxCreo Inc.
Review Panel: Dental

8. Device Description

LuxCreo Flexible Partial Denture (FPD) Resin is a state of the art resin engineered specifically for the 3D Printing of digitally designed flexible partial denture bases. The FPD resin utilizes LuxCreo's Digital Polishing platform to deliver clear, accurate, and biocompatible partial dentures in a single session with minimal need for finishing.

9. Comparison of Technological Characteristics with Predicate Devices

Please refer to Section 9 Substantial Equivalence Analysis for details.

10. Comparison of composition and Manufacturing Process with Reference Device

Please refer to Section 9 Substantial Equivalence Analysis for details.

11. Testing Summary

No.	Standard	Test Summary	Name of the Testing Lab/Qualification	Conformity Assessment	Report Name
1	EN ISO 10993-5:2009	In Vitro Cytotoxicity Test- 1. qualitative analysis 2. MTT method	Guangdong Neway Quality Technology Service Co. Ltd. /Registration No. CNAS L9783	No cytotoxicity	In Vitro Cytotoxicity Test_ WT24011077-11_
2	EN ISO 10993-10:2021	Skin Sensitization Test- Guinea Pig maximization test (Saline and Cottonseed Oil extract)		No delayed hypersensitivity	Skin Sensitization Test_ WT24011077-13
3	EN ISO 10993-23:2021	Oral Mucosa Irritation Test (Saline and Cottonseed Oil extract)		No oral mucosa irritation	Oral Mucosa Irritation Test_ WT24011077-14

4	EN ISO 10993-11:2017	Acute System Toxicity Test (Saline and Cottonseed Oil extract)		No acute systemic toxicity	Acute Systemic Toxicity Test Report_ WT24011077-12
5	EN ISO 10993-11:2017	Subacute Systemic Toxicity Test (Saline and Cottonseed Oil extract)		No sub-acute systemic toxicity	Subacute Systemic Toxicity Test_WT24011077-15
6	EN ISO 10993-11:2017	Subchronic System Toxicity Test (Saline and Sesame Oil extract, 90 days)		No subchronic systemic toxicity	Subchronic Systemic Toxicity Test_ WT24011077-16
7	EN ISO 10993-3:2014	Genotoxicity Test- 1. Bacterial reverse mytation assay (0.9% sodium chloride injection and dimethylsulfoxide extract) 2. In vitro mammalian chromosome aberration test (serum-free RPMI 1640 medium and dimethylsulfoxide extract)		No genotoxicity	1. Bacterial reverse mutation assay_WT24011077-19; 2. In Vitro Mammalian Chromosome Aberration Test_WT24011077-20

8	EN ISO 10993-6:2016	Impantation Test (subcutaneous implant, 13 weeks)		No local effects	Tests for Local Effects after Implatation_WT24011077-17
9	ISO 10993-18: 2020	Chemical Characterization	Centre Testing International Corporation Pinchuang (Shanghai) Co., Ltd.	Pass	Chemical Characterization Report_EL-REP-060.01.E
10	ISO 10993-17: 2023	Toxicological Risk Assessment	CTI Biotechnology (Suzhou) Co. Ltd.		Toxicological Risk Assessment Report_Assignment:2501182
11	ISO 20795-1:2013	Performance Test	Ningbo Sezen Technology Co., Ltd.	Complied with Technical Specifications	Section 16-1 FPD_Performance Test Report
12	ISO 20795-1:2013	Flexural Modulus and Flexural Strength Tests	Gold Standard Test (Guangdong) Co., Ltd.	Complied with Technical Specifications	Section 16-2 Performance Test Performance Test Report (Report No.: GW250808017）
13	ASTM D638-2014	Elongation at Break Test	Ningbo Sezen Technology Co., Ltd.	Complied with Technical Specifications	Section 16-1 FPD_Performance Test Report

12. Clinical Data

The nonclinical bench testing conducted in accordance with FDA-recognized consensus standards (ISO 20795-1 for denture base polymers) demonstrated that the subject device meets all applicable performance criteria for strength, durability, water resistance, and residual monomer content. Biocompatibility testing performed in accordance with ISO 10993-1, ISO 10993-5, ISO 10993-10, ISO 10993-11, and ISO 7405 confirmed that the device is non-cytotoxic, non-sensitizing, non-irritating, and does not pose systemic or genetic toxicity risks, establishing an acceptable biological safety profile for long-term mucosal contact. No clinical testing was required because the nonclinical evidence and comparison to legally marketed predicate devices with the same intended use and technological characteristics were sufficient to establish substantial equivalence. Taken together, the results demonstrate that the subject device is as safe, as effective, and performs as well as or better than the

identified predicate devices.

13. Substantial Equivalence Conclusion

Based upon the information presented, in terms of safety and effectiveness, the subject device is essentially equivalent to predicate devices.