April 8, 2025

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

Re: K250343
Trade/Device Name: LuxCreo Clear Aligner System
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: NXC
Dated: March 10, 2025
Received: March 10, 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,

Bobak Shirmohammadi -S

For Michael E. Adjodha, M.ChE., 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K250343

Device Name

LuxCreo Clear Aligner System

Indications for Use *(Describe)*

The LuxCreo Clear Aligner System is indicated for the treatment of tooth malocclusion in patients with permanent dentition (i.e. all second molars). The LuxCreo Clear Aligner System repositions teeth by way of continuous gentle force.

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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Section 20-3 Special 510 (k) Summary

A. 510(k) Number
K250343

B. Date Prepared
January 26, 2025

C. Submitter
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E. Device

- Device Name: LuxCreo Clear Aligner System
- Device Classification Name: Sequential Aligner
- Regulation Description: Orthodontic Plastic Bracket
- Regulation Number: 21 CFR 872.5470
- Device Class: Class II
- Product Code: NXC
- Review Panel: Dental

F. Indication(s) for Use

LuxCreo Clear Aligner System is indicated for the treatment of tooth malocclusion in patients with permanent dentition (i.e. all second molars). LuxCreo Clear Aligner System repositions teeth by way of continuous gentle force.

G. Predicate Device

- Device Name: LuxCreo Clear Aligner System
- 510(k) number: K212680
- Common Name: Sequential Aligner
- Regulation Name: Orthodontic Plastic Bracket
- Regulation Number: 21 CFR 872.5470
- Device Class: Class II
- Product Code: NXC
- Review Panel: Dental

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H. Device Description

Dental health professionals achieve orthodontic tooth movement through prescription of aligners which apply force to the patient's teeth so that each tooth follows a prescribed, predetermined displacement. LuxCreo Clear Aligner System is custom plastic aligner system which are a series of doctor prescribed clear removable aligners that are used as alternative treatment for the alignment of maloccluded or misaligned teeth. This series of aligners gently move the patient's teeth in small increments from their original state to a treated state.

A 3D printer, based on a 3D stereolithographic drawing, prints the predetermined shape of each aligner. Final polymerization is achieved by placing the printed aligner in a UV-light curing box. 3D printing uses specialty liquid resins, which help the aligners achieve mechanical properties similar to thermoplastics, and increased processability.

The aligners are packaged and labeled according to the sequence in which they are intended for use, determined by the prescribing dental health professional. The finished set of aligners is shipped with twelve-month-shelf-life to the prescribing physician, who is accountable for ensuring the patient uses the device properly and safely.

The LuxCreo Clear Aligner System mechanism of operation, and software usage, are identical to the predicate devices, and support a determination of substantial equality. Both the LuxCreo Clear Aligner System and the predicate devices are manufactured from a biocompatible, non-sterile polyurethane materials that supports a determination of substantial equality.

I. Comparison of Technical Logical Characteristics with the Predicate Device

LuxCreo Clear Aligner System and predicate devices (K212680) have:

1. Same intended use/ indication(s) for use
2. Same intended population
3. Same mode of action

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4. Same method of use
5. Same duration of use
6. Same required using software for ordering workflow
7. Removable devices
8. Same manufacturing process
9. Same biocompatibility evaluation and testing
10. Same technical specifications evaluation and testing
11. **Different materials**
12. **Different shelf life**

Material modification was made to the proposed device. The mechanical and chemical properties of the proposed device, including flexural modulus, flexural strength, shore D harness, stress relaxation, water solubility and water absorption, were assessed using the same test methods and pre-determined acceptance criteria. All the mechanical and chemical properties passed the tests successfully and demonstrates equivalent and/or better performance to the predicate device. The proposed device stability and packaging integrity were assessed using the same test method and pre-determined acceptance criteria. Test results verify the proposed device can be labeled with 12-month shelf life.

As presented in the 510(k) and summarized herein, LuxCreo Inc. concludes that the LuxCreo Clear Aligner System is substantially equivalent to predicate devices in regard to indications for use, design, and technology.

J. Substantial Equivalence Comparison Table – Manufacturing Process

Items	**Proposed Device (K250343)**	**Predicate Device (K212680)**
Method of Manufacturing	Same	Light-cured 3D printing

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Items	Proposed Device (K250343)	Predicate Device (K212680)
Technical Specifications of 3D Printing	Same	DLP/ SLA 3D printer UV cured 3D printing resin for medical device manufacturing.
Manufacturing process workflow	Same	Raw 3D printing material in combination with LuxCreo's manufacturing system.

K. Substantial Equivalence Comparison Table -Basic Information

Items	Proposed Device (K250343)	Predicate Device (K212680)
510(k) Number	TBD	K212680
Product Code	Same	NXC
Device Classification	Same	Class II
Intended Use/Indication(s) for Use	Same	The LuxCreo Clear Aligner System is indicated for the treatment of tooth malocclusion in patients with permanent dentition (i.e. all second molars). The LuxCreo Clear Aligner System repositions teeth by way of continuous gentle force.
Mode of Action	Same	Alignment of teeth by application of continuous gentle force, by sequential use by the dental practitioner. Orthodontic of preformed plastic trays.
Method of Use	Same	Each preformed plastic tray is worn by the patient as prescribed by the dental practitioner, usually a few weeks prior to using the next sequential

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Items	Proposed Device (K250343)	Predicate Device (K212680)
		aligner tray.
OTC/Rx	Same	Rx
Duration of Use	Same	20-22 hours/day
Method of Manufacturing	Same	Light-cured 3D printing

L. Substantial Equivalence Comparison Table – Physical and Mechanical Properties

Items	Proposed Device (K250343)	Predicate Device (K212680)
Ultimate Flexural Strength	34.61 ± 0.76 MPa	23.6 ± 1.9 MPa
Flexural Modulus	1040.02 ± 39.59 MPa	804 ± 64 MPa (ISO 20795-2:2013)
Shore D Hardness	63 ± 1.0 HD	21.63±0.38 HD
Stress Relaxation	41.56±0.0044%; No cracking was found.	37.3 ± 0.3%; No cracking was found.
Water solubility	0.39±0.04 $\mu g/mm^3$	3.668±1.0748 $\mu g/mm^3$
Water absorption	10.03±1.01 $\mu g/mm^3$	19.952±6.6719 $\mu g/mm^3$
Shelf Life	**12 Months**	6 Months

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M. Summary of Performance Data

The following performance data were provided to demonstrate substantial equivalence:

A. ISO 10993-3:2014 Genotoxicity test
B. ISO 10993-5 In vitro Cytotoxicity
C. ISO 10993-6:2016 Subcutaneous Implantation Test
D. ISO 10993-10 Oral Mucosa Irritation
E. USP Pyrogen Study
F. ISO 10993-10 Skin Sensitization (Maximization Test)
G. ISO 10993-11 Acute Systemic Toxicity
H. ISO 10993-11:2017 Sub-chronic systemic toxicity
I. Transportation and accelerating ageing tests were validated and completed.
J. Physical, chemical and mechanical properties were tested.
K. Design verification, validation and manufacturing validation were completed. All the results meet the product specification requirements.

N. Substantial Equivalence Conclusion

Based upon the information presented in this section, LuxCreo Inc. concludes that the LuxCreo Clear Aligner System is substantially equivalent to predicate device (K212680) in regard to indications for use, design, and technology.