Luxcreo Inc
% Ming-Yie Jan
Principle Consultant
RusCert Technology Co., Ltd
8F., No. 187, Lequn 2nd Rd.
Zhongshan Dist.
Taipei City, 10462
Taiwan

Re: K212680
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: February 24, 2022
Received: March 2, 2022

Dear Ming-Yie Jan:

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)*
K212680

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 5-510(k) SUMMARY

This 510 (K) summary is being submitted in accorndance with requirements of Title 21,CFR Section 807.92.

A.	510(k) NUMBER	**K212680**
B.	DATE PREPARED	May 24th, 2022
C.	SUBMITTER	LUXCREO INC. 940 Old County Road, Belmont, CA 94002 Registration Number: 3016237718 FEI Number: 3016237718 Tel:+1 650-3360227
D.	CONTACT PERSON	Primary Contact Person C.O.O. Mike Yang +1 650-336-0888 Mike.yang@luxcreo.com Second Contact Project Manager Jethro Wu 0970532485 Jethro.Wu@LuxCreo.com
E.	DEVICE	Proprietary Name: LuxCreo Clear Aligner System Common Name: Aligner, Sequential Product Code: NXC Regulation Number: 21 CFR 872.5470 Regulation Name: Orthodontic Plastic Bracket Device Class: Class II 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). The LuxCreo Clear Aligner System repositions teeth by way of continuous gentle force.

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G.	PRIMARY PREDICATE DEVICE	Proprietary Name:	ULab Systems Dental Aligner Kit
		Common Name:	Sequential Aligner
		Product Code:	NXC
		Regulation Number:	21 CFR 872.5470
		Regulation Name:	Orthodontic Plastic Bracket
		510(k) Number:	K192596
		510(k) Submitter:	uLab Systems, Inc.
		Device Class:	Class II
		Review Panel:	Dental
H.	SECONDARY PREDICATE DEVICE	Proprietary Name:	ClearCorrect System
		Common Name:	Sequential Aligner
		Product Code:	NXC
		Regulation Number:	21 CFR 872.5470
		Regulation Name:	Orthodontic Plastic Bracket
		510(k) Number:	K113618
		510(k) Submitter:	ClearCorrect LLC
		Device Class:	Class II
		Review Panel:	Dental
I.	PRIMARY REFERNCE DEVICE	Proprietary Name:	KeyPrint KeySplint Soft
		Common Name:	Mouthguard, Prescription/ Positioner, Tooth, Preformed
		Regulation Number:	No associated regulation/ 21 CFR 872.5525
		Classification Product Code:	MQC
		Subsequent Product Code:	KMY
		510(k) Number:	K183598
		510(k) Submitter:	Keystone Industries
		Device Class:	Unclassified, Class I
		Review Panel:	Dental
J.	SECONDARY REFERENCE DEVICE	Proprietary Name:	LuxaPrint Ortho Plus
		Common Name:	Prescription Mouthguard/ Resin, Denture, Relining, Repairing, Rebasing
		Regulation Number:	No associated regulation/ 21 CFR 872.3760

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Classification Product Code:	MQC
Subsequent Product Code:	EBI
510(k) Number:	K210940
510(k) Submitter:	DMG Digital Enterprises SE
Device Class:	Unclassified, Class II
Review Panel:	Dental

K. DEVICE DECRIPTION

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 six-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.

L. COMPARISON OF TECHNOLOGICAL

LuxCreo Clear Aligner System and predicate devices (K192596 and K113618) are:

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CHARACTERISTICS WITH THE PREDICATE DEVICES

1. Same intended use/ indication(s) for use
2. Same intended population
3. Same mode of action
4. Same method of use
5. Same duration of use
6. Required using software for ordering workflow
7. Removable devices
8. Different manufacturing process
9. Different materials

LuxCreo Clear Aligner System and reference devices (K183598 and K210940) are:

1. Same light-cured 3 D printing
2. Similiar DLP/ SLA 3D printer UV cured 3D printing resin for medical device manufacturing
3. Similar biocompatibility evaluation and testing.
4. Having software involved during the manufacturing ordering and manufacturing process.

The manufacturing process of LuxCreo Clear Aligner System is a light-cured, 3D printing process with light-cured polyurethane resin which is different from the thermoforming process of predicate devices. The biocompatibility risks have been considered. The biocompatibility tests indicated that the light-cured polyurethane resin is safe to use. The light-cured 3D printing process has also been used in the manufacturing of devices in dentistry. The difference in manufacturing process and base materials did not raise other safety and efficacy concerns.

LuxCreo Clear Aligner System and predicate devices (K192596 and K113618) are all the same intended use/ indication(s) for use, intended population, mode of action, method of use, removable devices which requires using a software for ordering workflow. The difference in manufacturing process and materials have been tested and validated. LuxCreo Clear Aligner System performed biocompatibility testing, physical and chemical properties testing of light-cured polyurethane resin.

Both KeyPrint KeySplint Soft, K183598, and LuxaPrint Ortho Plus, K210940, are using DLP/ SLA 3D printer with UV cured 3D printing resin for the intended use of orthodontic and dental appliances such as mouthguards, nightguards, splints and

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repositioners. The similar additive manufacturing and based materials between the LuxCreo Clear Aligner System and reference devices are substantially equivalent without extra concerns on their difference of properties.

As presented in the 510(k) and summarized herein, LUXCREO INC. concluded that LuxCreo Clear Aligner System is substantially equivalent to the predicate devices ULab Systems Dental Aligner Kit and the ClearCorrect System (K192596 and K113618) along with the reference devices KeyPrint KeySplint Soft (K183598) and LuxaPrint Ortho Plus (K210940).

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M. A COMPARISON TABLE WITH PREDICATE DEVICES

Items	**Proposed Device** LuxCreo Clear Aligner System	**Primary Predicate Device** ULab Systems Dental Aligner Kit	**Secondary Predicate Device** ClearCorrect System	**Substantial Equivalence Comparison Assessment**
510(k) Number	TBD	K192596	K113618	N/A
Product Code	NXC	NXC	NXC	Same
Device Classification	Class II	Class II	Class II	Same
Intended Use/ 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). The LuxCreo Clear Aligner System repositions teeth by way of continuous gentle force.	The uLab Systems Dental Aligner is indicated for the alignment of permanent teeth during orthodontic treatment of malocclusions by way of continuous gentle forces.	The ClearCorrect System is indicated for the treatment of tooth malocclusion in patients with permanent.dentition (i.e. all second molars). The ClearCorrect System positions teeth by way of continuous gentle force.	Same
Mode of Action	Alignment of teeth by application of continuous gentle force, by sequential use of preformed plastic trays	Each preformed plastic tray is worn in sequence by the patient as prescribed by the dental practitioner. Orthodontic movement occurs through continuous gentle forces applied to the dentition as each tooth follows the programmed displacement based on a doctor's prescription.	Alignment of teeth by application of continuous gentle force, by sequential use of preformed plastic trays	Same
Method of Use	Each preformed plastic tray is worn by the patient as prescribed by the dental practitioner, usually a few weeks prior to using the next	During the orthodontic treatment, each preformed plastic aligner is worn in sequence by the patient as prescribed by the dental practitioner, moving the patient's teeth gradually to	Each preformed plastic tray is worn by the patient as prescribed by the dental practitioner, usually a few weeks prior to using the next	Same

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Items	**Proposed Device** LuxCreo Clear Aligner System	**Primary Predicate Device** ULab Systems Dental Aligner Kit	**Secondary Predicate Device** ClearCorrect System	**Substantial Equivalence Comparison Assessment**
	sequential aligner tray	the ideal position.	sequential aligner tray	
OTC/Rx	Rx	Rx	Rx	Same
Duration of Use	20-22 hours/day	Each set of aligners can be worn for approximately 2 weeks of 20-22 hours of wear per day or according to doctor's prescription.	20-22 hours/day	Same
Method of Manufacturing	Light-cured 3 D printing	Thermoforming	Thermoforming	Different
Software Used for Ordering Workflow	Yes	Yes	Yes	Same
Application	Removable	Removable	Removable	Same
Biocompatibility	ISO 10993-5 In vitro Cytotoxicity ISO 10993-10 Oral Mucosa Irritation Pyrogen ISO 10993-10 Skin Irritation in Rabbits ISO 10993-10 Skin Sensitization in Guinea Pigs (Maximization Test) ISO 10993-11 Acute Systemic Toxicity	Raw materials: Cytotoxicity Elution -MEM Intracutaneous/Intradermal Reactivity Maximization for Delayed-Type Hypersensitivity Oral Mucosa Irritation Test Final product: Cytotoxicity Elution -MEM	ISO 10993-5 Cytotoxicity ISO 10993-10 Intracutaneous reactivity, oral mucosa irritation test, maximization test for delayed type hypersensitivity	Similar
Material	Light-cured polyurethane resin	Zendura A (thin thermoformed polyurethane) or Zendura FLX (copolyester and polyurethane composite)	Thermoplastic polyurethane resin	Different

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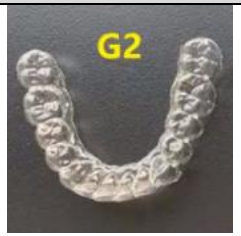
Items	Proposed Device LuxCreo Clear Aligner System	Primary Predicate Device ULab Systems Dental Aligner Kit	Secondary Predicate Device ClearCorrect System	Substantial Equivalence Comparison Assessment
Design				Similar design

N. Substantial Equivalence Comparison Table-Predicate Devices-- Mechanical Properties

Items	Proposed Device LuxCreo Clear Aligner System	Primary Predicate Device ULab Systems Dental Aligner Kit K192596	Secondary Predicate Device ClearCorrect System K113618	Substantial Equivalence Comparison Assessment
Ultimate Flexural Strength	23.6 ± 1.9 MPa	N/A	36.8±1.1 MPa (ISO 20795-2:2013)	Different
Flexural Modulus	1106.47±13.23 MPa (ASTM D790) 804 ± 64 MPa (ISO 20795-2:2013)	N/A	1122±24 MPa (ISO 20795-2:2013)	Different
Shore D Hardness	21.63±0.38 H_D	N/A	21.33±0.06 H_D	Similar
Stress Relaxation	37.3 ± 0.3% No cracking was found.	N/A	25.5 ± 0.4% No cracking was found.	Different

O. Substantial Equivalence Comparison Table-Reference Devices-Basic Information

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Items	**Proposed Device** LuxCreo Clear Aligner System	**Primary Reference Device** **KeyPrint KeySplint Soft**	**Secondary Reference Device** **LuxaPrint Ortho Plus**	**Substantial Equivalence Comparison Assessment**
510(k) Number	TBD	K183598	K210940	N/A
Product Code	NXC	MQC/ KMY	MQC / EBI	Different
Device Classification	Class II	Unclassified/ Class II	Unclassified/ Class II	Different
Intended Use/ 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). The LuxCreo Clear Aligner System repositions teeth by way of continuous gentle force.	The KeyPrint® KeySplint Soft™ device is indicated for the fabrication of orthodontic and dental appliances such as mouthguards, nightguards, splints and repositioners.	For the fabrication of orthodontic and dental appliances such as mouthguards, nightguards, splints and positioners. The product is for use with DLP/SLA printers that work at wavelengths of 385 nm or 405 nm.	Different
Mode of Action	Alignment of teeth by application of continuous gentle force, by sequential use of preformed plastic trays	It depends on the indications of final device.	The device consists of raw material that is used to fabricate removable custom dental appliances, such as orthodontic splints and/or mouthguards. The finished devices can be used to support tooth stabilization following active orthodontic treatment, and/or for the relief of bruxism or snoring. The device is used in conjunction with a	Different

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Items	**Proposed Device** LuxCreo Clear Aligner System	**Primary Reference Device** **KeyPrint KeySplint Soft**	**Secondary Reference Device** **LuxaPrint Ortho Plus**	**Substantial Equivalence Comparison Assessment**
			compatible scanner, 3D printer, and curing unit.	
Method of Use	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 aligner tray	Dental office/clinic, dental laboratory for appliance design and fabrication; home use for the resulting dental appliance.	Dental office/clinic, dental laboratory for appliance design and fabrication; home use for the resulting dental appliance.	Different
OTC/Rx	Rx	Rx	Rx	Same
Software Used for Ordering Workflow	Yes, a software is involved during the manufacturing ordering and manufacturing process. This device does not contain Software.	Yes, a software is involved during the manufacturing ordering and manufacturing process. This device does not contain Software.	Yes, a software is involved during the manufacturing ordering and manufacturing process. This device does not contain Software.	Same
Biocompatibility	ISO 10993-3:2014 Genotoxicity test ISO 10993-5 In vitro Cytotoxicity ISO 10993-6 Subchronic systemic toxicity ISO 10993-10 Oral Mucosa Irritation Pyrogen ISO 10993-10 Skin Irritation in Rabbits ISO 10993-10 Skin Sensitization in Guinea Pigs	ISO 10993-5 Cytotoxicity ISO 10993-10 Sensitization ISO 10993-10 Irritation	ISO 10993-1 Biocompatibility Assessment ISO 10993-5 Cytotoxicity ISO 10993-10 Irritation ISO 10993-10 Sensitization ISO 10993-3 Genotoxicity	Equivalent

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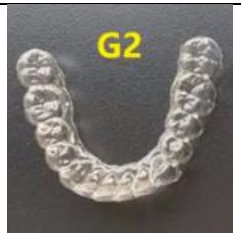
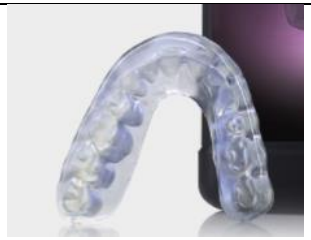
Items	Proposed Device LuxCreo Clear Aligner System	Primary Reference Device KeyPrint KeySplint Soft	Secondary Reference Device LuxaPrint Ortho Plus	Substantial Equivalence Comparison Assessment
	(Maximization Test) ISO 10993-11 Acute Systemic Toxicity ISO 10993-11 Subchronic systemic toxicity			
Material	Light-cured polyurethane resin	Light-cured polyurethane resin	Photocurable (meth)-acrylate-based polymer resin	Equivalent
Design				Similar

P. Substantial Equivalence Comparison Table- Reference Devices-Manufacturing Information:

Items	Proposed Device LuxCreo Clear Aligner System	Primary Reference Device KeyPrint KeySplint Soft K183598	Secondary Reference Device LuxaPrint Ortho Plus K210940	Substantial Equivalence Comparison Assessment
Method of Manufacturing	Light-cured 3 D printing	Light-cured 3 D printing	Light-cured 3 D printing	Same
Technical Specifications of 3D printing	DLP/ SLA 3D printer UV cured 3D printing resin for medical device manufacturing.	DLP/ SLA 3D printer UV cured 3D printing resin for medical device manufacturing.	DLP/ SLA 3D printer UV cured 3D printing resin for medical device manufacturing.	Same

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Items	Proposed Device LuxCreo Clear Aligner System	Primary Reference Device KeyPrint KeySplint Soft K183598	Secondary Reference Device LuxaPrint Ortho Plus K210940	Substantial Equivalence Comparison Assessment
Manufacturing process workflow	The raw 3D printing material in combination with LuxCreo's manufacturing system.	Raw 3D printing material	Raw 3D printing material	Different

Q. Substantial Equivalence Comparison Table-Physical and Mechanical Properties

Items	Proposed Device LuxCreo Clear Aligner System	Primary Reference Device KeyPrint KeySplint Soft K183598	Secondary Reference Device LuxaPrint Ortho Plus K210940	Substantial Equivalence Comparison Assessment
Flexural Strength	40.02±0.08 MPa (ASTM D790) 23.6 ± 1.9 MPa (ISO 20795-2:2013)	44-47 MPa (ASTM D790)	80 – 93 MPa (385 nm) 77 – 90 MPa (405 nm) (ISO 4049 & ISO 20795-2)	Different
Flexural Modulus	1106.47±13.23 MPa (ASTM D790) 804 ± 64 MPa (ISO 20795-2:2013)	1100-1400 MPa (ASTM D790) 135–200 MPa (ISO 20795-2)	1.9 – 2.4 GPa (385 nm) 2.1 – 2.5 GPa (405 nm) (ISO 4049 & ISO 20795-2)	Different
Shore D Hardness	21.63±0.38 HD	80–85 MPa (ASTM D2240)	≥ 60 (Cured material)	Different
Ultimate Flexural Strength	Ultimate flexural strength is 23.6 ± 1.9 MPa.	2.6–4.4 MPa (ISO 20795-2)	N/A	Different
Water Solubility	3.668±1.0748 µg/mm³	4.8 µg/mm³	1.5 – 3.6 µg/mm³ (385 nm) 0.7 – 2.1 µg/mm³ (405 nm) (ISO 4049 & ISO 20795-2)	Different
Water Sorption	19.952±6.6719 µg/mm³	18 µg/mm³	18.6 – 20.3 (385 nm) 17.1 – 17.7 µg/mm³ (405nm) (ISO 4049 & ISO 20795-2)	Similar

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R. SUMMARY OF PERFORMANCE DATA

The following performance data were provided to demonstrate the safety and efficacy:

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

S. SUBSTANTIAL EQUIVALENCE CONCLUSION

LuxCreo Clear Aligner System, ULab Systems Dental Aligner Kit, and the ClearCorrect System are intended to provide force to the user's teeth gently, and in small increments, from their original misalignment to their final treated position, for improved dental alignment. The difference in manufacturing process and base materials have not raised extra safety and performance concerns, based on the relevant tests and evaluations provided in this submission.

Both KeyPrint KeySplint Soft, K183598, and LuxaPrint Ortho Plus, K210940, are using DLP/ SLA 3D printer with UV cured 3D printing resin for the intended use of orthodontic and dental appliances such as mouthguards, nightguards, splints and repositioners. The additive manufacturing and based materials used for the LuxCreo Clear Aligner System and reference devices are substantially equivalent without extra concerns on their difference of properties.

Based upon the information presented in this section, LUXCREO INC. concludes that the LuxCreo Clear Aligner System is

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substantially equivalent to predicate devices in regard to indications for use, design, and technology.