September 1, 2023

Modern Dental Laboratory (DG) Co., Ltd.
% Robin Liu
Compliance Manager
Modern Dental Laboratory Co., Ltd.
Block 1 Modern Dental Industrial Park, No.7 Nantou
Songshan Lake Hi-Tech Industrial Zone
Dongguan, Guangdong 523000
CHINA

Re: K231884
Trade/Device Name: TRIOCLEAR System
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: NXC
Dated: August 4, 2023
Received: August 4, 2023

Dear Robin Liu:

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 -S

Michael E. Adjodha, M.ChE.
Assistant Director
DHT1B: Division of Dental and
ENT Devices
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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.

Submission Number *(if known)*

K231884

Device Name

TRIOCLEAR System

Indications for Use *(Describe)*

The TRIOCLEAR System is a series of clear, lightweight, plastic appliances indicated for the treatment of tooth malocclusions in patients with permanent dentition (i.e. all second molars). Utilizing a series of incremental tooth movement, it sequentially positions 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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510(k) Summary K231884

1. Submitter Information

Company Name:	Modern Dental Laboratory (DG) Co., Ltd.
Company Address:	Room 102&1102&Floor 4-10,Block 1 Modern Dental Industrial Park, No.7 Nantou, Songshan Lake Hi-Tech Industrial Zone 523000 Dongguan,Guangdong People's Republic of China
Company Phone:	T: 0769-22899211
Contact Person:	Robin Liu
Email:	Compliance@moderndentallab.com
Date Prepared	May 10, 2023

2. Device Identification

Device Model Name:	TRIOCLEAR System
Classification Name:	Orthodontic Plastic Bracket
Regulation Number:	872.5470
Product Code:	NXC
Class	II
Panel	Dental

3. Predicated Devices

Primary Predicate Device:	TRIOCLEAR System, K193622
Reference Device:	Clear Correct System, K220140

4. Device Description

The reason of this submission is that change raw material and the thickness types of TRIOCLEAR System in comparison to the primary predicate device TRIOCLEAR System (K193622).

The TRIOCLEAR System is a removable, non-sterile device intended for single patient use. TRIOCLEAR is a series of clear plastic aligners that offer a solution for patients who want an aesthetic orthodontic treatment by utilizing sets of removable aligners to correct tooth malocclusions without the use of conventional wire and bracket orthodontic technology.

5. Indications for Use

The TRIOCLEAR System is a series of clear, lightweight, plastic appliances indicated for the treatment of tooth malocclusions in patients with permanent dentition (i.e. all second molars). Utilizing a series of incremental tooth movement, it sequentially positions teeth by way of continuous gentle force.

6. Mechanism of Action

The mechanism of action is similar to the predicate device and supports a determination of substantial equivalence. Orthodontic tooth movement occurs through forces applied by the appliance to the dentition as each tooth follows the programmed displacement based on a dental health professional's prescription.

7. Technological Characteristics

A dental health care professional (e.g. orthodontist or dentist), prescribes the TRIOCLEAR System based on an assessment of the patient's teeth, determines a course of treatment with the system, takes physical or optical measurements of the patient's teeth and completes a prescription form. The measurements and prescription are sent to Modern DG.

Utilizing standard dental software used for tooth alignment, Modern DG designs a series of plastic trays intended to gradually realign the patient's teeth in accordance with the physician's prescription. The prescribing physician reviews and approves the model scheme before the molds are produced. Once approved, Modern DG produces the trays, which are formed of clear, thin thermoformed plastic. The trays are sent back to the dental health care professional, who then provides them to the patient, confirming fit and design. Over a period, additional trays are provided sequentially to the patient by the dental health care professional to gradually move the target teeth to the desired position.

The dental care professional monitors treatment from the moment the first aligner is delivered to when treatment is completed. The trays are held in place by pressure and can be removed by the patient at any time.

8. Performance Testing

The substantial equivalence of the device is supported by non-clinical testing. The verification and validation of the device performance testing was performed and found to be acceptable and supports the claims of substantial equivalence.

Some performance data got by testing as below:

Items	Standards requirement	Testing results	Conclusion
Water absorption value	≤ 32 μg/mm3	15 μg/mm3	Pass
Solubility value	≤ 5 μg/mm3	0.4 μg/mm3	Pass
Density	2.6 g/cm3	1.18 g/cm3	Pass
Sustained clamping force	≥ 1N	2.14-17.96 N	Pass
Flexural elastic modulus	≥ 600 MPa	1364.9MPa-1535.1MPa	Pass
Abrasive resistance	≤0.25g/1000r	0.0044g/1000r ~0.0074g/1000r	Pass
Tear resistance	＞200 N/cm	329.9N~489.4N	Pass
Thermostability	Mass change≤1%	0.03%	Pass
Right-angle tear strength	≥ 100 KN/m	217.2 KN/m	Pass
Tension attenuation	≤75%	54.6%	Pass
Stretch property	Stretch elastic modulus 700MPa ~ 3000MPa	970.11MPa	Pass
	Yield stress≥ 25 MPa	26.2 MPa	Pass
	Yield stretch strain ≥ 4%	5.9%	Pass
Reducing substance	The extract was compared with the same batch of blank control solution of equavolume. The difference in consumption of 0.002 mol/L KMnO4 solution should not exceed 2.0 mL .	0.15 mL	Pass
Heavy metal content	When determined by colorimetry, the color of the extract should not exceed the standard control solution	≤ 1 μg/mL	Pass

	with a mass concentration (Pb2+) = 1 μ g/mL.		
PH value	The difference between the PH value of the test solution and the blank control solution is not more than 1.5.	0.60	Pass
Evaporite	The total amount of evaporation residue ⩽ 2 mg.	0.4mg	Pass

9. Biocompatibility Testing

The biocompatibility evaluation for the thermoforming sheet was conducted in accordance with the US FDA CDRH Guidance Document Number 1811 "Use of International Standard ISO 10993-1, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process – Guidance for Industry and Food and Drug Administration Staff" as recognized by FDA.
The TRIOCLEAR System is physically stamped by thermoforming sheet without adding or removing any substance during the stamping process. Therefore, the biocompatibility of TRIOCLEAR System is substantial equivalence with thermoforming sheet.
The TRIOCLEAR System is considered mucosal membrane direct contacting for a duration of less than 30 days. The battery of testing included following tests:

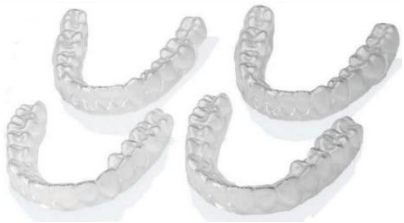
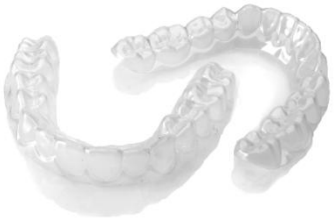
- Cytotoxicity
- Sensitization
- Irritation
- Bacterial Reverse Mutation
- In Vitro Mammalian Cell Gene Mutation

The result of the testing met the requirements of study plan and the thermoforming sheet is considered non-cytotoxic, non-sensitizing, non-irritant, no bacterial reverse mutation, no cell gene mutation. The biocompatibility of TRIOCLEAR System is substantial equivalence with thermoforming sheet, so the TRIOCLEAR System is also considered non-cytotoxic, non-sensitizing, non-irritant, no bacterial reverse mutation, no cell gene mutation.

10. Substantial Equivalence Comparison

The following table compares the TRIOCLEAR System to the primary predicate device TRIOCLEAR System(k193622) and reference device Clear Correct System (k220140) with respect to indications for use, technological characteristics and principles of operation, providing more detailed information regarding the basis for the determination of substantial equivalence.

Elements of Comparison	Subjective device	Primary Predicate Device	Reference Device	Explanation
Name	TRIOCLEAR System	TRIOCLEAR System	Clear Correct System	-
510(k) Number		K193622	K220140	-
Manufacturer	Modern Dental Laboratory (DG) Co., Ltd.	Perfection Aligner System Hong Kong Limited	ClearCorrect, LLC	-
Regulation Number	21 CFR 872.5470	21 CFR 872.5470	21 CFR 872.5470	-
Device Classification Name	Orthodontic plastic bracket	Orthodontic plastic bracket	Orthodontic plastic bracket	-
Classification Product Code	NXC	NXC	NXC	-
Device Class	Class II	Class II	Class II	-
Indications for Use	The TRIOCLEAR System is a series of clear, lightweight, plastic appliances indicated for the treatment of tooth malocclusions in patients with permanent dentition (i.e. all second molars). Utilizing a series of incremental tooth movement, it sequentially positions teeth by way of continuous gentle force.	The TRIOCLEAR System is a series of clear, lightweight, plastic appliances indicated for the treatment of tooth malocclusions in patients with permanent dentition (i.e. all second molars). Utilizing a series of incremental tooth movement, it sequentially positions teeth by way of continuous gentle force.	The ClearCorrect System is indicated for the alignment of teeth during orthodontic treatment of tooth malocclusion.	Identical
Material of Fabrication	Thermoplastic polyurethane-polyester composite resin	Thermoplastic (PET-G)	Thermoplastic polyurethane-polyester composite resin	The subject device and the reference device have the same general type of

				material of fabrication.
Material Properties	Demonstrates a high level of chemical resistance, abrasive resistance, tear resistance, Strength, elasticity, transparency, plasticity, excellent formability and stability for use as thermoforming sheet.	Demonstrates sufficient tensile strength, ductility, chemical resistance, and clarity for use as a clear tray aligner.	Demonstrates a high level of chemical resistance, abrasive resistance, tear resistance, Strength, elasticity, transparency, plasticity, excellent formability and stability for use as thermoforming sheet.	Identical
Design				Identical Appearance and shape is similar.
Mode of Action	Orthodontic tooth movement occurs through forces applied by the appliance to the dentition as each tooth follows the programmed displacement based on doctor's prescription. Two steps aligners will be worn by patient for each set.	Orthodontic tooth movement occurs through forces applied by the appliance to the dentition as each tooth follows the programmed displacement based on doctor's prescription. Three steps aligners will be worn by patient for each set.	The aligner is an orthodontic appliance intended for intra-oral use. Individual devices will be used between 20 – 22 hours per day for a period ranging from one to three weeks The corrective forces to align teeth are primarily generated by the difference between the starting tooth position and the planned tooth position defined by the tray. Features can be added to the aligner that engage with composite resin tooth attachments to improve aligner retention and/or to apply force in directions that cannot be achieved by	Equivalence The mode of operation of the Subject Device is identical to the Primary Predicate Device and is largely equivalence to the Reference Device.

			engaging with tooth surfaces alone.	
Treatment time	Each aligner should be worn for at least (20) hours per day.Each aligner should be changed every 7 days. Each step's changing time may change at the doctor's discretion, subjected to good compliance and fit as the patient progresses	Each aligner should be worn for at least (20) hours per day.Each aligner should be changed every 3-9 days. Each step's changing time may change at the doctor's discretion, subjected to good compliance and fit as the patient progresses.	Individual devices will be used between 20 – 22 hours per day for a period ranging from one to three weeks.	Equivalence The treatment is approved by a dentist, worn for an average of 20 hours a day, and requires regular checking
Technological Characteristics	Treatment of tooth malocclusion is via a series of plastic appliances that incrementally moves teeth to a desired end-state.	Treatment of tooth malocclusion is via a series of plastic appliances that incrementally moves teeth to a desired end-state.	The corrective forces to align teeth are primarily generated by the difference between the starting tooth position and the planned tooth position defined by the tray.	Equivalence The mode of operation of the Subject Device is identical to the Primary Predicate Device and is largely equivalence to the Reference Device
OTC or Rx	Rx	Rx	Rx	Identical

11. Substantial Equivalence Conclusion

Based on the above comparison between subjective device and primary predicate device, Reference Device demonstrates that the subjective device TRIOCLEAR System is as safe, as effective, and is substantially equivalent to the Primary predicate devices (K193622) and the Reference Device (K220140).