July 06, 2021

Perfection Aligner System Hong Kong Limited
Alwin Ngai
Director
Flat/Rm 4B, 4/F, Hang Fat Industrial Building, 550-556
Castle Peak Road
Kowloon, HONG KONG

Re: K193622
Trade/Device Name: TRIOCLEAR System
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: NXC
Dated: May 10, 2021
Received: June 2, 2021

Dear Alwin Ngai:

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)*
K193622

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.

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

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Section 5: 510(k) Summary

1. Submitter Information

Company Name:	Perfection Aligner System Hong Kong Limited
Company Address:	Flat/Rm 4B, 4/F, Hang Fat Industrial Building, 550-556 Castle Peak Road, Kowloon, Hong Kong
Company Phone:	(852) 3766 0737
Company Fax:	(852) 2577 7511
Contact Person:	Mr. Alwin Ngai
Email:	alwin.ngai@moderndentalgp.com
Date Prepared	June 29, 2021

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:	3M™ Clear Tray Aligner, K163689
Reference Device:	eCligner®, K143499

4. Device Description

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 devices 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 from. The measurements and prescription are sent to Perfection.

Utilizing standard dental software used for tooth alignment, Perfection 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, Perfection 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.

This technology is essentially identical to that used by a number of sequential alignment systems, including the predicated referenced below.

8. Performance Testing

Physical properties testing was conducted on the device. Tensile properties (tensile strength, modulus and elongation) were tested according to ISO 527-2. Hardness was tested according to ASTM D785. Humidity absorption was tested by immersion of specimen in distilled water during 24 hours at 23°C. All results of the above tests met the acceptance criteria.

The substantial equivalence of the device is supported by non-clinical testing. Validation was performed on the digital and 3D printed models, as well as the thermoformed aligners and the differences were calculated using a CAD overlay method and by using RMS calculations. All aligners fabricated met the pre-defined acceptance criteria and received an A grade for form and fit of the thermoformed aligners.

9. Biocompatibility Testing

The biocompatibility evaluation for the final finished device 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 considered mucosal membrane direct contacting for a duration of greater than 30 days. The battery of testing included following tests:

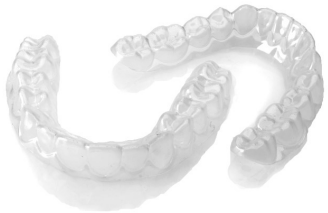
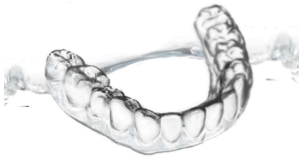
- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic Toxicity
- Pyrogenicity
- Subacute Toxicity
- Implantation

The result of the testing met the requirements of study plan and the TRIOCLEAR System is considered non-cytotoxic, non-sensitizing, non-irritant, no acute systemic toxicity, non-pyrogenic, no subacute repeated exposure systemic toxicity, and nonirritant when compared to implanted negative control article.

10. Substantial Equivalence Comparison

The following table compares the TRIOCLEAR System to the predicate devices 3M™ Clear Tray Aligner and eCligner® 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	Subject Device	Primary Predicate Device	Reference Device
Name	TRIOCLEAR System	3M™ Clear Tray Aligner	eClipner®
510(k) Number	K193622	K163689	K143499
Manufacturer	Perfection Aligner System Hong Kong Limited	3M Unitek Corporation	eClear International Co., Ltd.
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.	3M™ Clear Tray Aligner 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.	eClipner® is a series of clear, lightweight, plastic appliances indicated for the correction of dental malocclusion in patients with permanent dentition (i.e. all second molars). The eClipner® System is intended for minor anterior tooth movement by way of continuous gentle force.
Material of Fabrication	Thermoplastic	Thermoplastic	Thermoplastic

Material Properties	Demonstrates sufficient tensile strength, ductility, chemical resistance, and clarity for sue as a clear tray aligner.	Demonstrates sufficient tensile strength, ductility, chemical resistance, and clarity for sue as a clear tray aligner.	Demonstrates sufficient tensile strength, ductility, chemical resistance, and clarity for sue as a clear tray aligner.
Design			
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. Three 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. One single aligner 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.
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.	Treatment of tooth malocclusion is via a series of plastic appliances that incrementally moves teeth to a desired end-state.
OTC or Rx	Rx	Rx	Rx

11. Substantial Equivalence Conclusion

Based on the indications for use and performance information provided in this submission, demonstrates that the TRIOCLEAR System is as safe, as effective, and is substantially equivalent to the predicate devices.