November 12, 2020

TP Orthodontics Inc.
Stephanie Thyen
QA/RA Manager
100 Center Plaza
La Porte, Indiana 46350-9672

Re: K193385
Trade/Device Name: TP Orthodontics Clear Aligner System
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: NXC
Dated: September 24, 2020
Received: October 5, 2020

Dear Stephanie Thyen:

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 Srinivas “Nandu” Nandkumar, Ph.D.
Director
DHT1B: Division of Dental 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193385

Device Name
TP Orthodontics Clear Aligner System

Indications for Use *(Describe)*
TP Orthodontics Clear Aligner System consists of a series of 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 movements, TP Orthodontics Clear Aligner System 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.

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

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"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."

K193385

November 20, 2019

510(k) Summary

Submitter Information:

TP Orthodontics, Inc.
100 Center Plaza, La Porte, IN
Contact Person: Cristiane Muller
Phone Number: 1.800.348.8856 / 219.785.2591
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E-mail: cristiane.muller@tportho.com

Device Information:

Trade Name: TP Orthodontics Clear Aligner System
Common Name: Aligners, Sequential
Product Code: NXC
Classification Name: Orthodontic Plastic Bracket
Regulation Number: 872-5470
Device Class: II
Classification Panel: Dental

Predicate Devices:

Device	*Applicant*	*510(k) Number*
3M Clear Tray Aligner	3M Unitek Corporation	K163689

Reference Predicate Devices:

Device	*Applicant*	*510(k) Number*
Ortho System	3Shape A/S	K180941
Mouthguard and Aligner Material	Dentsply International	K062828
MTM Clear Aligner	Dentsply Sirona	K163155

Indications for Use:

TP Orthodontics Clear Aligner System consists of a series of 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 movements, TP Orthodontics Clear Aligner System sequentially positions teeth by way of continuous gentle force.

Device Description and Summary of Technological Characteristics:

TP Orthodontics Clear Aligner System consists of a custom-made series of plastic aligners that apply gentle pressure to teeth, gradually moving them into alignment.

A dentist or orthodontist assesses the patient to determine if the patient is a good candidate. Impressions are taken by the dental clinician and submitted to TP Orthodontics along with the physician's prescription.

TP Orthodontics, using a standard dental software used for teeth alignment, designs a series of plastic aligners intended to gradually realign the patient's teeth in accordance to the doctor's prescription. The set-up and intermediate stages are sent back to the physician for review and approval. Once the doctor

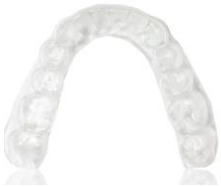
has approved the model scheme, the aligners are produced using a thermoplastic material and shipped to the dental practitioner.

The doctor delivers the aligners to the patient in sequential stages, provides instructions for use (such as when to change aligners), and monitors the case progression and fit and function from the first aligner through the end of treatment through follow-up appointments.

Aligners must be worn by the patient most of the day (20-22h), being removed only for eating, drinking and performing oral hygiene and should be replaced every 2-3 weeks as prescribed by the doctor.

Table 5.1. Substantial Equivalence Comparison

Characteristic	TP Orthodontics Clear Aligner System **Proposed Device**	**3M Clear Tray Aligner Primary Predicate**	**MTM Clear Aligner Reference Predicate**	**Comparison**
510(k)	To be determined	K163689	K163155	N/A
Manufacturer	TP Orthodontics, Inc.	3M Unitek Corporation	Dentsply Sirona/ Raintree Essix Inc.	N/A
Regulation Number	21 CFR 872.5470	21 CFR 872.5470	21 CFR 872.5470	Same
Device Classification Name	Orthodontic Plastic Bracket	Orthodontic Plastic Bracket	Orthodontic Plastic Bracket	Same
Product Code	NXC	NXC	NXC	Same
Device Class	Class II	Class II	Class II	Same
Indications for Use	TP Orthodontics Clear Aligner System consists of a series of 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 movements, TP Orthodontics Clear Aligner System sequentially positions teeth by way of continuous gentle force.	The 3M Clear Tray Aligner 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 movements, it sequentially positions teeth by way of continuous gentle force.	MTM® Clear Aligner is indicated for the treatment of anterior tooth malocclusions in patients with permanent dentition (i.e. all second molars). Utilizing a series of incremental minor tooth movements, MTM® Clear Aligner sequentially positions teeth by way of continuous gentle force.	Similar. The verbiage of the indications for use is slightly different than the primary and reference predicates, however, these slight differences in wording do not change the intended use of the subject device in relation to the predicate devices and does not raise any new questions about safety and effectiveness.
Intended Population	Individuals with permanent dentition	Individuals with permanent dentition	Individuals with permanent dentition	Same
Material	Co-polyester or co-polymer; Thermoplastic	Thermoplastic	Co-polyester or co-polymer; Thermoplastic	Similar. All devices are made of a biocompatible thermoplastic material.
Mode of action	Continuous gentle forces applied to teeth to attain orthodontic tooth movement.	Continuous gentle forces applied to teeth to attain orthodontic tooth movement.	Continuous gentle forces applied to teeth to attain orthodontic tooth movement.	Same

Characteristic	TP Orthodontics Clear Aligner System **Proposed Device**	**3M Clear Tray Aligner Primary Predicate**	**MTM Clear Aligner Reference Predicate**	**Comparison**
Method of Use	Aligners are worn by the patient according to the treating doctor prescription.	Aligners are worn by the patient according to the treating doctor prescription.	Aligners are worn by the patient according to the treating doctor prescription.	Same
Software Used for Ordering Workflow	Yes	Yes	Yes	Same
Prescription (Rx) or Over-the-Counter (OTC)	Rx	Rx	Rx	Same
Design of Aligners				Same. All are comprised of clear thermoplastic trays that seat over the teeth.

Clinical Performance Data

The clinical performance of sequential aligners (product code NXC) has been well established since the first device of this category was cleared by the FDA in 1998. TP Orthodontics Clear Aligner System have equivalent indication and method of use to its primary and reference predicate devices, therefore there was no clinical testing to support this device.

Non-Clinical Performance Data

A manufacturing validation was performed to ensure the dimensional accuracy of TP Orthodontics Clear Aligner System and assess the integration between the steps of the manufacturing process. The validation demonstrated that the aligners manufactured match the software output specifications. Physical properties testing was obtained from the clearance for the Aligner Material from Dentsply, 510(k) K062828.

Biocompatibility Testing

Biocompatibility tests were not performed as TP Orthodontics Clear Aligner System are made of the same material (thermoplastic material) as its primary and reference predicate devices. The material used (Aligner Material from Dentsply, 510(k) K062828) is the same used in the fabrication of MTM aligners (reference predicate device), and therefore there are no differences in biocompatibility between them. Biocompatibility testing data was obtained from the clearance for the Aligner Material from Dentsply, 510(k) K062828.

Software Verification and Validation Testing

Both software used with TP Orthodontics Clear Aligner System passed their validations.

Substantial Equivalence Conclusion

TP Orthodontics Clear Aligner System presents substantially equivalent indication for use and technological characteristics as its primary and reference predicate devices. There are slight differences in the language of the indications for use, however these differences do not impact safety and efficacy of the device.

It is concluded that TP Orthodontics Clear Aligner System is safe, effective, and substantially equivalent to its primary and reference predicate devices.