February 9, 2023

AMPA Orthodontics Private Limited
% Sanjeev Gupta
Managing Consultant
Intrust
A301/A Green Heritage, Plot 79-80, Sector 20
Kharghar, Maharashtra 410210
India

Re: K223338
Trade/Device Name: Toothsi&SmileAligners
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: NXC,
Dated: October 29, 2022
Received: November 1, 2022

Dear Sanjeev Gupta:

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,

Bobak Shirmohammadi -S

For Michael Adjodha, M.ChE.,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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223338

Device Name
Toothsi&SmileAligners

Indications for Use *(Describe)*

The patient specific set of Clear Dental Aligners are indicated for the treatment of tooth malocclusion in patients having permanent dentition. These Aligners position teeth by way of continuous gentle force. These are for self-use by patient with monitoring of improvement by orthodontists.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

510 k Summary - Substantial Equivalence Discussion K223338

A. **Name and Address of Manufacturer**:

AMPA Orthodontics Private Limited
1st Floor, Empire Plaza B Wing
Lal Bahadur Shastri Marg
Vikhroli West
Mumbai 400083
Maharashtra, India
Phone/Fax: +91 9820340245
Contact Person: Dr. Manjul Jain (drmanjul@toothsi.in)

B. **Device Details**:

a) Trade Name: Toothsi & SmileAligners

b) Common Name: Clear Dental Aligners

c) Classification Name: Aligner, Sequential

d) Product Code: NXC

C. **Predicate Device**: ClearCorrect System (**K113618)**

D. **Device Description**: The Clear Dental Aligners are thermoformed, orthodontic wearable & removable dental appliances that, when worn in the prescribed sequence and duration, progressively reposition the permanent malocclusion teeth. These aligners could be soft, medium, or hard as per prescription set by an orthodontist, and to exert the desired & continuous gentle force to progressively position the teeth. Each aligner is made of thermoforming BPA free material sheets.

E. Intended Use The patient specific set of Clear Dental Aligners are indicated for the treatment of tooth malocclusion in patients having permanent dentition. These Aligners position teeth by way of continuous gentle force. These are for self-use by patient with monitoring of improvement by orthodontists.

1st floor, Empire Plaza B Wing, Lal Bahadur Shashtri Marg, Vikhroli (West), Mumbai - 400083

+91 9898000000
Info@toothsi.in
www.toothsi.in

F: Comparison of proposed device with predicate device for

Table 1: Showing technological characteristics between Toothsi and ClearCorrect (Predicate Device)

Equivalence Points	Clear Dental Aligners	ClearCorrect System (K113618)	Comparison
Manufacturer	AMPA Orthodontics Pvt. Ltd.	CLEARCORRECT LLC	N/A
Product Code	NXC	NXC	Equivalent
Regulation Number	21 CFR 872.5470	21 CFR 872.5470	Equivalent
Intended Use/Indications for Use	The patient specific set of Clear Dental Aligners are indicated for the treatment of tooth malocclusion in patients having permanent dentition. These Aligners position teeth by way of continuous gentle force. These are for self-use by patient with monitoring of improvement by orthodontists.	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	Equivalent
Mechanism of Action	Continuous gentle force to move the teeth	Continuous gentle force to move the teeth	Equivalent
Material of Construction	Thermoplastic	Thermoplastic	Equivalent
Aligner Material Thickness (For different aligner set)	~0.5 mm to ~1.0 mm as per treatment plan	Soft (0.5 mm) Medium (0.62 mm) Hard (0.75 mm) Ultra Hard (1 mm)	Equivalent
Biocompatible	Complies with ISO 10993 (FR# 2-248 & 2-296)	ISO 10993-1	Equivalent
Prescription Steps	Approximately 7-14 days/aligner set as per prescription	Soft (1 Week) Medium (1 Week) Hard (1 Week)	Equivalent
Daily Duration of wear	At least 20-22 hours	17 hours a day	Equivalent
Sterile	Non-Sterile	Non-Sterile	Equivalent
Single-Use	Single User Use	Single User Use	Equivalent

1st floor, Empire Plaza B Wing, Lal Bahadur Shashtri Marg, Vikhroli (West), Mumbai - 400083
+91 9898000000
Info@toothsi.in
www.toothsi.in

G. Performance Testing Bench (Non-clinical)

The following bench testing was performed as part of Design Verification with purpose define in column 2 of Table 2 below. The reports are presented in sequence along with data tables and figures as applicable in **018_Performance Testing Bench**. No separate annexure has been created for this section.

Table 2: Summary of bench testing performed on design samples of clear dental aligners			Test Outcome
Sr. No	Purpose of Bench Testing	Report Number	
1	Surface finishing after polishing by two methods	**Report No. AO/DV/R1 dated 31-12-2021**	**Accepted**
2	Thickness of aligners after thermoforming with reference to aligner sheets	**Report No.: AO/DV/R2 Dated 31-12-2021**	**Accepted**
3	Aligner shape accuracy after mimicked use for 15 days	**Report No.: AO/DV/R7 Dated 10-01-2022**	**Accepted**
4	3D Model shape accuracy for effectiveness of aligner punching as per treatment plan	**Report No.: AO/DV/R3 Dated 10-01-2022**	**Accepted**

The above four tests relate to safety (Sr. No 1 & 4) and performance (Sr. No 2, 3 and 4) of the clear aligners. No comparative testing with predicate device was possible since clear dental aligners are patient specific devices made after treatment plan.

H. Substantial Equivalence Discussion

Comparison of specifications with predicate device: The Section F-Table 1 above summarizes the comparison of subject device with predicate device.

a) **Similarities**: As it emerges from the review of Section F-Table 1 the characteristics related to Intended Use, Mechanism of Action, Material Thickness, Material of Construction, Prescription Steps are equivalent between predicate and subject devices.

b) **Differences**: The duration of wearing aligner is around 17 hours in predicate device and around 22 hours for subject device. This difference is subjective and does not alter safety and performance of the devices. Such difference majorly emerges from the user actions.

1st floor, Empire Plaza B Wing, Lal Bahadur Shashtri Marg, Vikhroli (West), Mumbai - 400083
+91 9898000000
Info@toothsi.in
www.toothsi.in

c) **Standards Testing**: AMPA Orthodontics Private Limited has performed biocompatibility testing of the subject device by application of ISO 10993 standards which has also been followed by the predicate device manufacturer.

Conclusions: We, therefore, conclude that Clear Dental Aligner manufactured by AMPA Orthodontics Private Limited have substantial equivalence with ClearCorrect Aligners **(**K113618) Manufactured by ClearCorrect LLC.

1st floor, Empire Plaza B Wing, Lal Bahadur Shashtri Marg, Vikhroli (West), Mumbai - 400083

+91 9898000000
Info@toothsi.in
www.toothsi.in