Straight Smile, LLC
% Craig Coombs
President
Coombs Medical Device Consulting, Inc.
1193 Sherman St
Alameda, California 94501

February 19, 2019

Re: K180346
Trade/Device Name: Byte Aligner System
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: NXC
Dated: November 24, 2018
Received: November 26, 2018

Dear Craig Coombs:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mary S. Runner -S3

Digitally signed by Mary S. Runner -S3
Date: 2019.02.19 09:02:26 -05'00'

For Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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)*
K180346

Device Name
Byte Aligner System

Indications for Use *(Describe)*
The Byte Aligner System is indicated for the treatment of tooth malocclusion in patients with permanent dentition (i.e., all second molars). The Byte Aligner System 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."

K180346: 510(k) Summary

A. Device Information:

Category	Comments
Sponsor:	Straight Smile, LLC; dba: Byte 370 Alabama St., Ste K Redlands, California 92373 Office phone: 1.818.231.2363 Fax Number: 1.512.727.0429 E-mail: sabbasi@byteme.com Contact: Sepi Abbasi, Managing Member
Correspondent Contact Information:	Craig Coombs Coombs Medical Device Consulting 1193 Sherman Street Alameda, CA 94501 Tel: 510-337-0140 Fax: 510-337-0416
Device Common Name:	Sequential Aligners
Device Classification Number:	21 CFR 872.5470
Device Classification & Product Code:	Class II, NXC
Device Proprietary Name:	Byte Aligner System

Predicate Device Information:

Predicate Device:	ClearCorrect System
Predicate Device Manufacturer:	ClearCorrect, Inc
Predicate Device Common Name:	Sequential Aligners
Predicate Device Premarket Notification #	K113618
Predicate Device Classification:	21 CFR 872.5470
Predicate Device Classification & Product Code:	Class 2, NXC

Reference Device Information:

Reference Device:	Smart Moves Complete
Reference Device Manufacturer:	Great Lakes Orthodontics Ltd
Reference Device Common Name:	Sequential Aligners
Reference Device Premarket Notification #	K172765
Reference Device Classification:	21 CFR 872.5470
Reference Device Classification & Product Code:	Class 2, NXC

B. Date Summary Prepared

11 February 2019

C. Description of Device

The Byte Aligner System is a series of Byte dental aligners fabricated of clear, thin thermoformed polyethylene terephthalate glycol (PETG) plastic to progressively reposition the teeth. Corrective force to straighten the teeth is delivered via minor changes into a modified position in each subsequent aligner.

D. Indications for Use

The Byte Aligner System is indicated for the treatment of tooth malocclusion in patients with permanent dentition (i.e., all second molars). The Byte Aligner System positions teeth by way of continuous gentle force.

E. Comparison to Predicate/Reference Devices

The Straight Smile Byte Aligner System is substantially equivalent in intended use, indications for use, mode of action, mode of use, design and materials to the predicate ClearCorrect System (K113618).

Both devices have identical Indications for Use, except for the device name, which implies they have the same intended use.

Both devices have the same modes of action and use. Both are a sequential series of rigid aligners that gently pressure the teeth to move in a desired manner. The patient transitions to the next aligner in the series approximately every two weeks. After completing the series, the user's teeth should conform to the desired position.

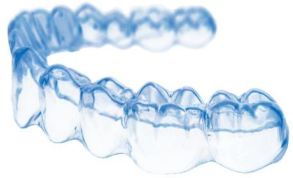
The application and predicate aligners are made from different base materials. The predicate aligners are made from thermoplastic polyurethane. The Byte aligners are made from thermoplastic PETG. PETG has been used in other dental appliances and aligners, including the reference device Smart Moves Complete sequential aligners (K172765). Straight Smile conducted testing that demonstrated that the PETG material can be manufactured into aligners and meet the same safety and performance criteria as the predicate and reference devices.

The testing described below demonstrates that the differences in the devices do not raise any unresolved issues of safety or efficacy.

Straight Smile concludes that the predicate ClearCorrect System (K113618) and the application Byte Aligner System are substantially equivalent.

Substantial Equivalence Justification Table

	PREDICATE DEVICE **ClearCorrect System** **ClearCorrect, Inc.** **K113618**	**REFERENCE DEVICE** **Smart Moves Complete** **Great Lakes Orthodontics Ltd** **K172765**	**APPLICATION DEVICE** **Byte System** **Straight Smile, LLC**	**Substantial Equivalence Analysis**
Common Name	Sequential Aligner	Sequential Aligner	Sequential Aligner	Identical to both predicate and reference devices
Classification #	872.5470	872.5470	872.5470	Identical to both
Product Code	NXC	NXC	NXC	Identical to both
Indication for Use	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.	Smart Moves Complete is indicated for the treatment of tooth malocclusion in patients with permanent dentition (i.e. all second molars). Smart Moves Complete positions teeth by way of continuous gentle force.	The Byte Aligner System is indicated for the treatment of tooth malocclusion in patients with permanent dentition (i.e., all second molars). The Byte Aligner System positions teeth by way of continuous gentle force.	Identical to both**,** except for device name
Intended Population	Individuals with permanent dentition	Individuals with permanent dentition	Individuals with permanent dentition	Identical to both
Mode of Action	Orthodontic tooth movement occurs through forces applied by the device to the dentition as each tooth follows the programmed displacement based on a doctor's prescription.	Orthodontic tooth movement occurs through forces applied by the device to the dentition as each tooth follows the programmed displacement based on a doctor's prescription.	Orthodontic tooth movement occurs through forces applied by the device to the dentition as each tooth follows the programmed displacement based on a doctor's prescription.	Identical to both
Anatomical Site of Use	Oral cavity	Oral cavity	Oral cavity	Identical to both

	PREDICATE DEVICE **ClearCorrect System** **ClearCorrect, Inc.** **K113618**	**REFERENCE DEVICE** **Smart Moves Complete** **Great Lakes Orthodontics Ltd** **K172765**	**APPLICATION DEVICE** **Byte System** **Straight Smile, LLC**	**Substantial Equivalence Analysis**
Mode of Use	Each aligner is worn by the patient as determined by the treating dental practitioner, generally for 2 weeks prior to being replaced by the next aligner in sequence. This is repeated for a duration as prescribed by a Dental Professional.	Each aligner is worn by the patient as determined by the treating dental practitioner, generally for 2 weeks prior to being replaced by the next aligner in sequence. This is repeated for a duration as prescribed by a Dental Professional.	Each aligner is worn by the patient as determined by the treating dental practitioner, generally for 2 weeks prior to being replaced by the next aligner in sequence. This is repeated for a duration as prescribed by a Dental Professional.	Identical to both
Application	Removable	Removable	Removable	Identical to both
Raw Material Used	Thermoplastic polymers (polyurathane)	Thermoplastic polymers (polyethylene terephthalate glycol or PETG)	Thermoplastic polymers (polyethylene terephthalate glycol or PETG)	Identical to Reference device. Used in same way.
OTC or Rx	Rx	Rx	Rx	Identical to both
Design				Design is developed and fabricated by similar or identical processes used by predicate and reference devices

F. Summary of Supporting Data

Biocompatibility analysis demonstrates that the Byte Aligner System is in compliance with ISO 10993. Testing included:

Cytotoxicity
Sensitization

Information was provided to demonstrate that PETG is commonly used for dental appliances and in other aligners.

Bench testing has demonstrated that the device is in compliance with pertinent standards and specifications, the expectations of the dental community and the product labeling.

Straight Smile validated the manufacturing process of the Byte aligners, demonstrating that the process can adequately render the final device as specified by appropriate FDA-cleared design software.

Straight Smile validated the 2-year shelf life of the aligners with real-time testing.

G. Conclusion

The Byte Aligner System is substantially equivalent to the predicate device (ClearCorrect System: K113618) in indications for use, design, technological characteristics, mechanism of action, performance, materials and biocompatibility.