August 31, 2022

Key Dental Technologies, LLC
℅ Thomas Padula
Vice President of Regulatory Compliance
Schiff & Company, Inc.
583 Mountain Avenue
North Caldwell, New Jersey 07006

Re: K221475
Trade/Device Name: MyClearALIGN Dental Aligner System
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: NXC
Dated: May 19, 2022
Received: July 19, 2022

Dear Thomas Padula:

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.

Submission Number *(if known)*

K221475

Device Name

MyClearALIGN Dental Aligner System

Indications for Use *(Describe)*

The MyClearALIGN Dental Aligner System is indicated for the alignment of all permanent teeth/full permanent dentition during orthodontic treatment of malocclusions by way of continuous gentle forces.

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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510(k) #: K221475

510(k) Summary

Prepared on: 2022-07-18

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Key Dental Technologies, LLC
Applicant Address	920 MLK Blvd Suite 920-B Chapel Hill NC 27517 United States
Applicant Contact Telephone	919-259-2280
Applicant Contact	Dr. Larry Moray
Applicant Contact Email	dr.larrymoray@myorthodontistus.com
Correspondent Name	Schiff & Company, Inc.
Correspondent Address	583 Mountain Avenue North Caldwell NJ 07006 United States
Correspondent Contact Telephone	201-317-8810
Correspondent Contact	Mr. Thomas Padula
Correspondent Contact Email	thomaspadula@schiffandcompany.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	MyClearALIGN Dental Aligner System
Common Name	Orthodontic plastic bracket
Classification Name	Aligner, Sequential
Regulation Number	872.5470
Product Code	NXC

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K192596	ULab Systems Dental Aligner Kit	NXC

Device Description Summary

21 CFR 807.92(a)(4)

MyClearALIGN Dental Aligner System device is a clear aligner system fabricated using the commercially available Zendura FLX, a clear, thin thermoformed Copolyester – Polyurethane Composite with 2 outer layers of cycloaliphatic polyester and an inner layer of polyether polyurethane. The pressure areas create forces that combine to form couples and thus a moment around or near the center of resistance or center of rotation of the tooth. A series of aligners is fabricated to sequentially move the teeth from their original position to positions of better alignment. Each set of aligners is designed to be replaced after
approximately 2 weeks of 20-22 hours of wear per day (Approximately 300 hours per aligner). Each tooth is moved no greater than 0.25mm in one aligner stage (approximately 2 weeks of 20-22 hours of wear per day).

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The MyClearALIGN Dental Aligner System is indicated for the alignment of all permanent teeth/full permanent dentition during

orthodontic treatment of malocclusions by way of continuous gentle forces.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The indications for use are the same as the predicate device.

Technological Comparison 21 CFR 807.92(a)(6)

The subject and predicate device are based on the following same technological elements:

- Both devices are clear plastic sequential aligners.
- Both devices have the same intended use for alignment of teeth during orthodontic treatment of malocclusions by way of continuous gentle forces.
- Both devices have the same indications for use.
- Both devices have the same principle of operation.
- Both devices are fabricated based on an orthodontic treatment plan designed by the aligner manufacturer's technicians from digital scans of the patient's teeth in an untreated state.
- Both devices are made of thermoplastic (Zendura-FLX).

MyClearALIGN Dental Aligner System is substantially equivalent in terms of the technological characteristics, features, specifications, materials, mode of operation and indications for use, to uLab Systems Dental Aligner K192596, cleared for marketing under 510(K).

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

A series of studies were completed to demonstrate the substantial equivalence of MyClearALIGN Dental Aligner System to the predicate device. All testing was conducted in accordance with and in conformance to applicable device regulations and guidance. Results of all testing demonstrate the device is non-toxic, is comparable to other currently marketed devices and is substantially equivalent to legally marketed predicate and included:

Biocompatibility
- ISO 10993-3:2014, biological evaluation of medical devices – part 3: tests for genotoxicity carcinogenicity and reproductive toxicity.
- ISO 10993-5:2009, biological evaluation of medical devices -- part 5: tests for in vitro cytotoxicity. (Biocompatibility).
- ISO 10993-10 :2010, biological evaluation of medical devices - part 10: tests for irritation and skin sensitization. (Biocompatibility).
- ISO 10993-11 Third edition 2017-09 biological evaluation of medical devices part 11: Tests for systemic toxicity

Performance Testing Bench
The following Bench testing was performed:
- FLX E2 Zendura XL Design Verification Report_TROUSER TEAR_#18-14 Rev 1
- FLX E3 Zendura XL Design Verification Report - Light Transmission and Haze #18-10 Rev 1
- FLX E4 Zendura XL Thermoforming Verification Report #18-15 Rev 1
- FLX E17 Zendura XL Report - Compatible with Commercial Denture Disinfectant #17-31
- FLX E18 Zendura XL Report - Exposure to Common Beverages #17-022
- FLX E19 Zendura XL Report - Extended 37C Saline Exposure #17-33
- FLX E20 Zendura XL Report - Extended 47C Saline Exposure 17-26
- FLX E21 Zendura XL Report - Outdoor Exposure Effects#17-024
- Zendura FLX Stain _25Jan2018
- Zendura XL Design Verification Report - Flexural Properties #17-44 Rev 1
- Zendura XL Design Verification Report - Tensile&Elongation #17-46 Rev 1
- Zendura XL Design Verification Report- Stain Resistance #18-05 Rev1
- Zendura XL Design Verification Report- Stress Relaxation #18-24 Rev 1

Performance Testing Clinical
There were no clinical studies performed.

MyClearALIGN Dental Aligner System has the same indications for use and technology characteristics as the predicate device. MyClearALIGN Dental Aligner System is as safe, as effective, and performs as well as the predicate device.