April 5, 2024

Park Dental Research Corporation
% Logan Simmons
Regulatory Affairs Consultant
Prime Path Medtech
1321 Upland Dr. Suite 6792
Houston, Texas 77043

Re: K233935
Trade/Device Name: DigiLine Direct Print Aligner System
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: NXC
Dated: March 19, 2024
Received: March 19, 2024

Dear Logan Simmons:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

FDA Bobak Shirmohammadi -S

For Michael E. Adjodha, M. ChE., RAC, 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K233935

Device Name

DigiLine Direct Print Aligner System

Indications for Use *(Describe)*

The DigiLine Direct Print Aligner System is indicated for the treatment of tooth malocclusion in patients with permanent dentition (i.e. all second molars). The DigiLine Direct Print Aligner System repositions 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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510(k) Summary

Prepared on: 2024-03-19

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Prime Path MedTech
Applicant Address	1321 Upland Drive Suite 6792 Houston TX 77043 United States
Applicant Contact Telephone	440-387-9788
Applicant Contact	Mrs. Logan Simmons
Applicant Contact Email	lsimmons@primepathmedtech.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	DigiLine Direct Print 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
K223355	Tera Harz Clear	NXC
K212680	LuxCreo Clear Aligner	NXC

Device Description Summary

21 CFR 807.92(a)(4)

The Proposed Device, DigiLine Direct Print Aligner System consists of multiple stages of 3D printed plastic aligners designed to be worn in sequence to facilitate the movement of a patient's teeth to the final desired treatment position. The sequential stages of aligners introduce incremental movements that move teeth by way of gentle continuous force to achieve a more optimal bite profile. The aligners are to be worn 20 to 22 hours a day and are to be removed for eating and for cleaning.

The Proposed Device is designed from digital scans of a patient's dentition submitted by a dental health professional (e.g. dentist or orthodontist). Using the scan, sequential stages of dental models are designed and approved by a physician prior to physical manufacturing. Once the treatment plan is reviewed and approved by a dental health professional, each aligner stage is fabricated by additive manufacturing, specifically 3D printing. The 3D printed aligner then undergoes post-processing and cleaning prior to packaging for patient use. DigiLine Direct Print Aligner System are direct-printed using DigiLine Direct Print Resin. DigiLine Direct Print Resin is a light-cured, methacrylate-based resin. Methacrylate-based resins are commonly used for the production of dental structures.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

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

Indications for Use Comparison

21 CFR 807.92(a)(5)

The Proposed Device in this submission is the same as the Predicate Device (Tera Harz Clear, K223355) as they are both indicated for use in the alignment of teeth through orthodontic treatment of malocclusion. It can be used permanent dentition with a wear time 20 to 22 hours a day for 1-2 weeks or as prescribed by the treating physician.The differences between the indications for use of the Proposed Device, Predicate Device (Tera Harz Clear, K223355), and the previously cleared Reference Device (LuxCreo Clear Aligner, K212680) do not raise questions of substantial equivalence. The Proposed Device guides patients' teeth to their desired treated position by way of continuous gentle forces in sequential aligner stages. The Predicate Device (Tera Harz Clear, K223355) indication does not differ from the Proposed device in the
functionality of the device. The Predicate (Tera Harz Clear, K223355) also lists compatible orthodontic software, 3D printers and curing units. The indications for use is the exact same as the Reference Device (LuxCreo Clear Aligner, K212680). Thus, the Proposed Device can be considered substantially equivalent to the Predicate Device (Tera Harz Clear, K223355) and Reference Device (LuxCreo Clear Aligner, K212680).

Technological Comparison 21 CFR 807.92(a)(6)

The technological characteristics of DigiLine Direct Print Aligner System is the same as that of the Tera Harz Clear (K223355). Both products are fabricated from a methacrylate-based resin that undergoes a UV curing process to harden the appliance. Thus, DigiLine Direct Print Aligner System can be considered substantially equivalent to its predicate device.

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

Performance Testing was conducted in accordance with ISO 20795-2:2013.
A manufacturing validation was performed to demonstrate that the additive manufacturing process is capable of successfully fabricating DigiLine Direct Print Aligner System. The validation confirmed the dimensional accuracy of the manufacturing process and the quality of the aligners resulting from the process. The test met the pre-established acceptance criteria.

Additionally, material testing was conducted on the aligner material according to internal design specification and with the applicable performance standards (ISO 20795-2:2013). Biocompatibility testing for the aligner material, the only patient contacting aspect, was conducted in accordance with International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process." All testing met the requirements of the applicable standard.

Clinical Testing was not required for the Predicate Device or the DigiLine Direct Print Aligner System.

Testing has demonstrated that the DigiLine Direct Print Aligner System is as safe, as effective, and performs as well as or better than the legally marketed devices referenced above.