October 13, 2023

ClearAdvance, LLC
℅ Logan Simmons
Regulatory Affairs Consultant
Prime Path Medtech
1321 Upland Dr. Suite 6792
Houston, Texas 77043

Re: K232429
Trade/Device Name: Titan Dental Design
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: PNN, LLZ
Dated: August 11, 2023
Received: August 11, 2023

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,

Michael E. Adjodha -S

Michael E. Adjodha, MChE, RAC, CQIA
Assistant Director
DHT1B: Division of Dental and
ENT Devices
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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)*

K232429

Device Name
Titan Dental Design

Indications for Use *(Describe)*
Titan Dental Design is intended for use as a medical front-end device providing tools for management of orthodontic models, systematic inspection, detailed analysis, treatment simulation and virtual appliance design options (Export of Models, Indirect Bonding Transfer Media, Sequential aligners) based on 3D models of the patient's dentition before the start of an orthodontic treatment. It can also be applied during the treatment to inspect and analyze the progress of the treatment. It can be used at the end of the treatment to evaluate if the outcome is consistent with the planned/desired treatment objectives.

The use of Titan Dental Design requires the user to have the necessary training and domain knowledge in the practice of orthodontics, as well as to have received a dedicated training in the use of the software.

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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Section 5. 510(k) Summary

K232429

510(k) SUMMARY

A summary of 510(k) safety and effectiveness information for this traditional 510(k) in accordance with the requirements of 21 CFR 807.92.

Submitter: CLEARADVANCE, LLC
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Phone: 440-387-9788
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Date Prepared: August 1, 2023

Proprietary Name: Titan Dental Design

Common Name: Orthodontic Plastic Bracket (Software)

Product Code: PNN – Orthodontic plastic bracket (Software), LLZ

Device Classification: Class II, 21 CFR 872.5470

Primary Predicate Device: 3Shape Ortho System (K152086)

Second Predicate Device: Brius Planner Software (K212828)

Device Description:

Titan Dental Design by ClearAdvance, LLC is an orthodontic appliance design and treatment planning software. This software is for use by dentists, orthodontists, and trained health care professionals to diagnose and design treatment solutions for patients. The Titan Dental Design software allows users to upload digital scans of patient's dentition to the system, manipulate and move teeth in the dentition scan

to create treatment plans for malocclusion, and export or send treatment planning files for physical production of orthodontic appliances such as thermoplastic aligners with the use of 3D printers.

Indications for Use:

Titan Dental Design is intended for use as a medical front-end device providing tools for management of orthodontic models, systematic inspection, detailed analysis, treatment simulation and virtual appliance design options (Export of Models, Indirect Bonding Transfer Media, Sequential aligners) based on 3D models of the patient's dentition before the start of an orthodontic treatment. It can also be applied during the treatment to inspect and analyze the progress of the treatment. It can be used at the end of the treatment to evaluate if the outcome is consistent with the planned/desired treatment objectives.

The use of Titan Dental Design requires the user to have the necessary training and domain knowledge in the practice of orthodontics, as well as to have received a dedicated training in the use of the software.

Comparison to Predicate Devices:

The Proposed Device is functionally equivalent to the following devices: 3Shape Ortho System (K152086, cleared April 28, 2016) and Brius Planner Software (K212828, cleared 10/01/2021). The following table demonstrates the functional specifications of the Proposed Device are substantially equivalent to the Predicate Devices and raises no questions regarding safety and effectiveness of the device.

Table 5 Device Comparison Table

Specification	**Proposed Device:** Titan Dental Design	**Primary Predicate Device:** 3Shape Ortho System (K152086)	**Predicate Device: BRIUS Planner Software (K212828)**	**Comparison Result**
Regulation Number	21 CFR 872.5470	21 CFR 872.5470	21 CFR 872.5470	Same
Classification Name	Orthodontic Plastic Bracket (Software)	Orthodontic Plastic Bracket (Software)	Orthodontic Plastic Bracket	Same
Product Code	PNN, LLZ	PNN, LLZ	PNN	Same
Classification	Class II	Class II	Class II	Same
Indication for Use	Titan Dental Design… is intended for use as a medical front-end device providing tools for management of orthodontic models, systematic inspection, detailed analysis, treatment simulation and virtual appliance design options (Export of Models,	The 3Shape Ortho System™ … is intended for use as a medical front-end device providing tools for management of orthodontic models, systematic inspection, detailed analysis, treatment simulation and virtual appliance design options (Custom Metal	BRIUS Planner Software… is intended for use as a medical front-end device providing tools for management of orthodontic models, systematic inspection, treatment simulation and virtual appliance design options (Patient-Specific Nitinol Wires,	Similar

Specification	**Proposed Device:** Titan Dental Design	**Primary Predicate Device:** 3Shape Ortho System (K152086)	**Predicate Device: BRIUS Planner Software (K212828)**	**Comparison Result**
	Indirect Bonding Transfer Media, Sequential aligners) based on 3D models of the patient's dentition before the start of an orthodontic treatment. It can also be applied during the treatment to inspect and analyze the progress of the treatment. It can be used at the end of the treatment to evaluate if the outcome is consistent with the planned/desired treatment objectives. The use of Titan Dental Design requires the user to have the necessary training and domain knowledge in the practice of orthodontics, as well as to have received a dedicated training in the use of the software.	Bands, Export of Models, Indirect Bonding Transfer Media) based on 3D models of the patient's dentition before the start of an orthodontic treatment. It can also be applied during the treatment to inspect and analyze the progress of the treatment. It can be used at the end of the treatment to evaluate if the outcome is consistent with the planned/desired treatment objectives. The use of the Ortho System™ requires the user to have the necessary training and domain knowledge in the practice of orthodontics, as well as to have received a dedicated training in the use of the software.	Sequential Aligners, Export of Models, Indirect Bonding Transfer Media) based on 3D models of the patient's dentition before the start of an orthodontic treatment. It can also be applied during the treatment to inspect and analyze the progress of the treatment. It can be used at the end of the treatment to evaluate if the outcome is consistent with the planned/desired treatment objectives. The use of the BRIUS Planner requires the user to have the necessary training and domain knowledge in the practice of orthodontics, as well as to have received a dedicated training in the use of the software	

Specification	**Proposed Device:** Titan Dental Design	**Primary Predicate Device:** 3Shape Ortho System (K152086)	**Predicate Device: BRIUS Planner Software (K212828)**	**Comparison Result**
Technological Features	• Stand Alone Software • Imports Digital Dental Scans • Can be used to design Dental Appliances • Useful for Diagnosis, treatment planning, and CAD design • Virtual Planning of tooth movement	• Stand Alone Software • Imports Digital Patient Scans • Can be used to design Dental Casts • Useful for Diagnosis, treatment planning, and CAD design • Virtual Planning of tooth movement	• Stand Alone Software Module • Imports Digital Patient Scans • Can be used to design Dental Casts • Useful for Diagnosis, treatment planning, and CAD design • Virtual Planning of tooth movement • Supports STL Files	Similar
Minimum Hardware/Software Requirements	• **OS:** Android: Firmware Version 8.0 Oreo or higher, iOS: Firmware Version 10 or higher, Windows, Mac • **RAM:** 4 GB RAM • **Video Card:** 1 GB GPU • **Hard Drive Space:** 4 GB • **CPU:** 2.6 GHz • **Web browser (Titan Dental Design):** Windows: .exe, Mac: .pkg, Android: ,apk, IOS: .ipa • **Internet Access**	• **OS:** Windows 7, 8, 64-bit • **RAM:** 8 GB • **Video Card Memory:** 1 GB GeForce • **Hard Drive Space:** 250 GB • **CPU**: Intel Core i5 or equivalent • **Network Internet Connection** • **Mouse**: with wheel button	• **OS:** Windows 10 64-bit • **RAM:** 8 GB • Monitor Resolution:1280 X 800 • **Video Card Memory:** 1 GB • **Hard Drive Space:** 10 GB • **CPU:** Intel compatible 2.6 GHz/Dual or Quad core 2.6 GHz • **Mouse:** Any Mouse with scrolling wheel or button	Similar
Login Method	Username and password	Username and password	Username and password	Same
Supported Anatomic Areas	Maxilla/Mandible	Maxilla/Mandible	Maxilla/Mandible	Same
<u>Intended Use</u>				

Specification	**Proposed Device:** Titan Dental Design	**Primary Predicate Device:** 3Shape Ortho System (K152086)	**Predicate Device: BRIUS Planner Software (K212828)**	**Comparison Result**
Managing Patient and case base data	Yes	Yes	Yes	Same
Collection of study material	Yes	Yes	Yes	Same
Alignment of study material	Yes	Yes	Yes	Same
Measuring study material	Yes	Yes	Yes	Same
Analyzing study material	Yes	Yes	Yes	Same
Treatment simulation	Yes	Yes	Yes	Same
Virtual appliance design	Yes	Yes	Yes	Same
Surface scan for intraoral scanner	Yes	Yes	Yes	Same
Surface scan from STL file	Yes	Yes	Yes	Same
Arch shape	Yes	Yes	Yes	Same
Overbite/overjet	Yes	Yes	Yes	Same
Occlusal map	Yes	Yes	Yes	Same
3D treatment simulation	Yes	Yes	Yes	Same
Orthodontic	Yes	Yes	Yes	Same
Appliance virtual preparation	Yes	Yes	Yes	Same
Orthodontic appliance design	Yes	Yes	Yes	Same
Orthodontic appliance export	Yes	Yes	Yes	Same
Creating, editing, and copying patient data	Yes	Yes	Yes	Same
Creating, editing, and copying case	Yes	Yes	Yes	Same

Specification	Proposed Device: Titan Dental Design	Primary Predicate Device: 3Shape Ortho System (K152086)	Predicate Device: BRIUS Planner Software (K212828)	Comparison Result
data				

Comparison of Indications for Use to the Predicate Devices:

Based on the above comparison, the indications of use of the Proposed Device is similar to that of the Predicate Devices. The alteration of indication for use statement to the Predicate Device (3Shape Ortho System, K152086) within this 510(k) submission of the Proposed Device is "intended for use as a medical front-end device providing tools for management of orthodontic models, systematic inspection, detailed analysis, treatment simulation and virtual appliance design options (Custom Metal Bands, Export of Models, Indirect Bonding Transfer Media) based on 3D models of the patient's dentition before the start of an orthodontic treatment". The proposed device, Titan Dental Design, manufactures sequential aligners, rather than Custom Metal Bands like those manufactured by the Predicate Device. However, the secondary Predicate Device's (Brius Planner Software, K212828), indication for use statement matches the indications for use statement of the Proposed Device in that it lists Sequential Aligners as one of its "virtual appliance design options",

Based on the similarity of indication for use, the Proposed Device can be considered substantially equivalent to the Predicate Devices.

Comparison of Technological Characteristics to Predicate Devices:

Based on the above comparisons, the design, construction, and performance characteristics of the Proposed Device are similar to that of the Predicate Devices. The differences identified are not substantial differences in operation of the device. Thus, the Proposed Device can be considered substantially equivalent to the Predicate Devices.

Summary of Performance Data and Substantial Equivalence

Utilizing FDA Guidance document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" (issued May 11, 2015) the Proposed Device, Titan Dental Design underwent appropriate integration, verification, and validation testing. The software passed the testing and performed per its intended use.

Conclusion:

Based on comparison of indications for use, technological features, performance testing, and software validation testing, the Proposed Device, Titan Dental Design, has been shown to be appropriate for its indications for use and is substantially equivalent to the legally marketed Predicate Devices, 3Shape Ortho System (K152086) and Brius Planning Software (K212828)