January 25, 2022

CDB Corporation
Leah Lehman
Senior Operations Manager
9201 Industrial Boulevard, NE
Leland, North Carolina 28451

Re: K212173
Trade/Device Name: HDH Treatment Planning System
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: PNN, LLZ
Dated: December 29, 2021
Received: January 4, 2022

Dear Leah Lehman:

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.

510(k) Number *(if known)*
K212173

Device Name
HDH Treatment Planning System

Indications for Use *(Describe)*
The HDH Treatment Planning 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 design of a series of dental casts, which may be used for sequential aligner trays or retainers, based on 3D models of the patient's dentition. The use of the HDH Treatment Planning System requires the user to have the necessary training and domain knowledge in the practice of orthodontics, as well 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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510(k) Summary

This 510(k) Summary is submitted in accordance with the requirements of 21CFR 807.92

Submitter: CDB Corporation
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Establishment Registration No.: 1054415

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Date Prepared:	January 12, 2022
510k Submission:	K212173
Device Name:	HDH Treatment Planning System
CFR Classification:	21 CRF 872.5470
Device Classification Name:	Orthodontic Plastic Bracket
Product Code:	PNN (Orthodontic Software), LLZ (System, image processing, radiological)
Common Name:	Orthodontic Treatment Planning & Diagnosis Software
Classification:	Medical Device, Class II

Indications for Use:
The HDH Treatment Planning 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 design of a series of dental casts, which may be used for sequential aligner trays or retainers, based on 3D models of the patient's dentition. The use of the HDH Treatment Planning System requires the user to have the necessary training and domain knowledge in the practice of orthodontics, as well to have received a dedicated training in the use of the software.

Predicate Device:
3Shape Ortho System, 3Shape A/S, K152086 (primary predicate)
HIT Clear Aligner, CDB Corporation, K210613 (reference device)

Device Description:
The HDH Treatment Planning system is a software system for orthodontic diagnosis and treatment simulation utilized by dental professionals. The software imports patient 3D digital scans serving as a base for diagnosing the orthodontic treatment needs, analyzing, inspecting, measuring, and simulating tooth movements, and allows the user to develop a virtual treatment plan. The output of the treatment plan may be downloaded as files in STL format, a standard stereolithographic file format, or OBJ format, a standard 3D image format, for fabrication of dental casts, which may be used to fabricate sequential aligner trays or retainers.

Technological characteristics:
The HDH Treatment Planning system is a software device programmed in C++ with the following hardware requirements:

Item	Minimum Requirements
OS:	Windows 8 or 10, 64 bit
RAM:	>=8 GB
Monitor Resolution:	1280x800
Video Card Memory:	>=1GB
Available HDD Space:	10 GB
CPU:	Intel core i5 2500 or equivalent
Network:	Network Internet connection
Mouse:	With the wheel button

The above hardware requirements are found to be substantially equivalent to the requirements of 3Shape Ortho System ™, FDA cleared per K152086.

Performance Data:

Software verification and validation testing was performed in accordance with the FDA Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" (issued May 11, 2005).

All test results met acceptance criteria, demonstrating the HDH Treatment Planning System performs as intended and is substantially equivalent to the predicate devices.

Substantial Equivalence Discussion:

The following table compares the HDH Treatment Planning System to the predicate device, 3Shape Ortho System ™, with respect to indications for use, technological characteristics, and principles of operation. The reference device, HIT Clear Aligner, is also presented in the comparison table.

Table 1. Predicate Device Information Comparison

Feature	HDH Treatment Planning System	3Shape Ortho System ™	HIT Clear Aligner
	Submission Device	**Predicate Device**	**Reference Device**
510(k) Number	K212173	K152086	K210613
Manufacturer	CDB Corporation	3Shape A/S	CDB Corporation
Regulation Number	872.5470	872.5470	872.5470
Device Classification Name	Orthodontic Plastic Bracket	Orthodontic Plastic Bracket	Orthodontic Plastic Bracket
Product Code	PNN (Orthodontic Software) LLZ (System, image processing, radiological)	PNN (Orthodontic Software) LLZ (System, image processing, radiological)	NXC (Aligner, Sequential)
Common Name	Orthodontic Treatment Planning and Diagnosis Software	Orthodontic Treatment Planning and Diagnosis Software	Aligner, Sequential
Device Class	II	II	II
Indications for Use	The HDH Treatment Planning 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 design of a series of dental casts, which may be used for	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 Bands, Export of Models, Indirect Bonding Transfer Media)	The HIT Clear Aligner system is indicated for the treatment of malocclusion in patients with permanent dentition. The HIT Clear Aligner system positions teeth by way of continuous gentle force.

	sequential aligner trays or retainers, based on 3D models of the patient's dentition. The use of the HDH Treatment Planning System requires the user to have the necessary training and domain knowledge in the practice of orthodontics, as well to have received a dedicated training in the use of the software.	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.	
Operating principle	The software provides calculation displaying the recommended sequential aligners staging on the patient's teeth, based on the pre-treatment 3D scanned orthodontic model, clinician-prescribed treatment objective and clinician's general pre-treatment preferences.	The software provides calculation displaying virtual appliance design options based on 3D models of a patient's dentition.	Alignment of teeth by sequential use of preformed plastic trays.
Key records	3D models are generated from scanned analog impressions or directly from an intra-oral scan.	3D scanned orthodontic models	From the software part: 3D models are generated from scanned analog impressions or directly from an intra-oral scan.
Software end product	Dental casts	Custom metal bands, indirect bonding transfer trays and dental casts	Dental casts
Application of digital imaging tools based on 3D orthodontic models for orthodontic case archiving, diagnosis, treatment planning and CAD design	Yes	Yes	Yes

Virtual planning of orthodontic treatments simulating tooth movements	Yes	Yes	Yes
Supported types of digital data	STL, OBJ	DICOM, STL, JPG, BMP, PNG	STL, OBJ
OTC or Rx	Rx	Rx	Rx

The software output for the predicate device is represented by custom metal bands, indirect bonding transfer trays and dental casts, whereas the subject device designs only dental casts.

Clinical Testing:
Clinical testing is not a requirement and has not been performed.

Substantial Equivalence Conclusion:
By definition, a device is substantially equivalent when the device has the same intended use and the same technological characteristics as the predicate device. The subject and the primary predicate devices share the same intended use including software used by dental professionals in orthodontic treatment planning for management of patients and orthodontic models, inspection, measurement and analysis of the models, treatment simulation, preparation and export of a series of virtual dental casts. The subject and the primary predicate devices share the same operating principle.

The software output for the predicate device is represented by custom metal bands, indirect bonding transfer trays and dental casts, whereas the subject device designs only dental casts. The difference in the software output along with the supported types of digital data is insignificant and do not require further testing to ensure the correct product operation; thus, the difference does not affect safety or efficacy of the subject device.

The subject and predicate devices share digital imaging tools based on 3D orthodontic models for orthodontic case archiving, diagnosis, treatment planning and CAD design, and virtual planning of orthodontic treatments simulating tooth movements.

Performance data demonstrates that any differences in technological characteristics do not raise different questions of safety or effectiveness.

The conclusion drawn from the data included in this submission demonstrates that the HDH Treatment Planning system is substantially equivalent to the cleared predicate device.