June 4, 2021

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

Re: K210613
Trade/Device Name: HIT Clear Aligner
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: NXC
Dated: May 4, 2021
Received: May 6, 2021

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
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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)*
K210613

Device Name
HIT Clear Aligner

Indications for Use *(Describe)*
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.

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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# 510(k) Summary – Special 510(k)

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

Submitter: CDB Corporation
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Date Prepared: June 2, 2021

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| 510k Submission: | K210613 |
| Proprietary Trade Name: | HIT Clear Aligner |
| Common Name: | Sequential Aligner |
| Classification Name: | Orthodontic Plastic Bracket |
| Regulation Number: | 872.5470 |
| Product Code: | NXC |
| Classification Panel: | Dental Products Panel 76 |
| Classification: | Medical Device, Class II |

**Indications for Use:**

**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.**

**Predicate Devices:**

Clear-Aligners, CDB Corporation, K191823 (primary predicate)
Arcad SmileStudio and Aligner System, ArcadLab, LLC, K192244 (reference device)

**Device Description:**

A dental health care professional (e.g., orthodontist or dentist), using a standard personal computer prescribes the HIT Clear Aligner system based on an assessment of the patient's teeth, determines a course of treatment with the system, takes molds of the patient's teeth, and completes a prescription form.

The modification of the primary predicate device is a software system for orthodontic diagnosis and treatment simulation, HDH Treatment Planning software, utilized by CDB to design a series of plastic trays intended to gradually realign the patient's teeth in accordance with the physician's prescription. The software uses 3D scanned orthodontic models of a patient's dentition as input files serving as a base for diagnosing the orthodontic treatment needs, analyzing, inspecting, measuring, and simulating tooth movements, thereby allowing to create virtual treatment plans. 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.

The prescribing physician reviews and approves the treatment plan before the molds are produced. Once approved, CDB produces the trays, which are formed of clear, thin, thermoformed, copolyester plastic. The trays sent back to the dental health care professional, who then provides them to the patient, confirming fit and design. Over a period of months, additional trays are provided sequentially to the patient by the dental health professional to gradually move the target teeth to the desired position. The dental care professional monitors treatment from the moment the first aligner is delivered to when the final aligner is delivered. The trays are held in place by pressure and can be removed by the patient at any time. This technology is essentially identical to that used by a number of sequential alignment systems, including the predicates referenced in Table 1.

As part of the original 510(k), K191823, materials and dimensions, labeling, sterilization and shelf life, biocompatibility, and clinical performance testing data remain unchanged in comparison to the primary predicate. In addition, sections not applicable to the original 510(k) submission – Class III Summary and Certification, Financial Certification or Disclosure Statement, Declaration of Conformity and Summary Reports, Electromagnetic Compatibility and Electrical Safety, Performance Testing Data – Animal – remain unchanged in comparison to the primary predicate.

**Technological Characteristics:**

Treatment of tooth malocclusions via a series of plastic appliances that incrementally moves teeth to a desired end-state is the technological principle for both the subject and predicate devices.

In comparison to the primary predicate device, the modified device includes proprietary software, HDH Treatment Planning software, that provides tools for management of patients and orthodontic models, systematic inspection, detailed analysis, treatment simulation and virtual design of a series of dental casts. The software provides calculation displaying the recommended sequential aligners staging on the patient's teeth, based on the initial 3D scanned orthodontic model, clinician-prescribed treatment objective and the clinician's general pre-treatment preferences.

A comparison between technological characteristics of the HIT Clear Aligner and that of legally marketed predicate devices has been performed and referenced in Table 1. The results of this comparison demonstrate that the design, technology, materials, and composition of the HIT Clear Aligner is substantially equivalent to the predicate devices.

**Mechanism of Action:**

The mechanism of action is similar to the predicate devices and supports a determination of substantial equivalence. Orthodontic tooth movement occurs through forces applied by the appliance to the dentition as each tooth follows the programmed displacement based on a dental health professional’s prescription.

**Performance Testing:**

A process qualification was re-executed to ensure the accuracy of the final product carried through the entire process from the initial scan through treatment planning and manufacturing of the model to the final thermoformed aligner, demonstrating the software change created no adverse impact to the final product.

Results of verification and validation testing demonstrated device conformity with preestablished specifications from the original submission. Thus, the HIT Clear Aligner system performs as intended and is substantially equivalent to the primary predicate device.

The HDH Treatment Planning software uses the system of eXceed Computerized Precision Bracket Placement Solution software, which was FDA cleared per K150702, to produce different orthodontic dental appliances.

**Biocompatibility Testing:**

Because materials are unchanged in comparison to the primary predicate, the biological evaluation for the primary predicate device conducted in accordance with the FDA Guidance Document, “Use of International Standard ISO 10993-1, Biological evaluation and testing within a risk management process – Guidance for Industry and Food and Drug Administration Staff” as recognized by FDA, is still effective for the modified device.

The results of the testing documented as part of the original submission, including cytotoxicity, sensitization, and irritation tests, met the requirements of the study protocols and the material is considered non-cytotoxic, non-sensitizing, and is not an intracutaneous irritant. The results of the studies provided for the primary predicate further support the determination of substantial equivalence.

**Software Consideration:**

There are two areas in the HIT Clear Aligner process where software is used; they are the ordering process and treatment planning.

The only modification compared to the primary predicate is the proprietary software for treatment planning which provides calculation displaying the recommended sequential aligners staging on the patient's teeth, based on the initial 3D scanned orthodontic model, clinician-prescribed treatment objective and the clinician's general pre-treatment preferences.

Software testing has been performed within the process qualification procedure to verify the function of the HIT Clear Aligner, which supports a substantial equivalence decision.

**Substantial Equivalence Comparison:**

The following table compares the HIT Clear Aligner system to the predicate devices, Clear- Aligners (primary predicate) and Arcad SmileStudio and Aligner System (reference device), with respect to indications for use, technological characteristics, and principles of operation.

**Table 1. Predicate Device Information Comparison**

| Feature | HIT Clear Aligner | Clear-Aligners | Arcad Lab Aligner and Arcad Smile Studio |
|---|---|---|---|
| | **Submission Device** | **Primary Predicate** | **Reference Device** |
| **510(k) Number** | K210613 | K191823 | K192244 |
| **Manufacturer** | CDB Corporation | CDB Corporation | ArcadLab, LLC |
| **Regulation Number** | 872.5470 | 872.5470 | 872.5470 |
| **Device Classification Name** | Aligner, Sequential | Aligner, Sequential | Orthodontic plastic bracket<br>Orthodontic software |
| **Product Code** | NXC | NXC | NXC, PNN |
| **Device Class** | II | II | II |
| **Indications for Use** | 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. | The Clear-Aligner system is indicated for the treatment of malocclusion in patients with permanent dentition. The Clear-Aligner system positions teeth by way of continuous gentle force. | The ArcadLab SmileStudio 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 before the |

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| | | | 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.<br><br>The ArcadLab Aligner System is indicated for the treatment of tooth malocclusion in patients with permanent dentition (i.e. all second molars). The ArcadLab Aligner System positions teeth by way of continuous gentle force.<br><br>The use of the ArcadLab SmileStudio and Aligner 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. |
| **Mode of Action** | Alignment of teeth by sequential use of preformed plastic trays. | Alignment of teeth by sequential use of preformed plastic trays. | Alignment of teeth by sequential use of preformed plastic trays. |
| **Material** | Thermoformed Copolyester | Thermoformed Copolyester | Thin thermoformed polyurethane |
| **Proprietary Treatment Planning Software** | Yes – system includes proprietary software<br><br>The HDH Treatment Planning software is used by dental professionals in orthodontic treatment planning (before, during, after treatment) covering management of patients and orthodontic models, inspection, 2D and 3D measurement, orthodontic analysis of models, 2D & 3D treatment simulation, as well as virtual appliance | No – system includes standard dental software used for tooth alignment<br><br>The standard software is 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 plastic trays intended to gradually realign the | Yes – system includes proprietary software<br><br>The software is used by Dental Professionals in orthodontic treatment planning (before, during, after treatment) covering management of patients and models, inspection, 2D and 3D measurement, orthodontic analysis of models, 2D & 3D treatment simulation, as well as virtual appliance preparation, handling and export. Also provides CAM output for 3D printers and milling machines. |

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| | preparation, handling, and export. The software also provides CAM output for milling machines. | patient's teeth. The output for 3D printers and milling machines is provided by utilizing CAD-CAM software. | |
| **OTC or Rx** | Rx | Rx | Rx |

The subject and the 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.

**Substantial Equivalence Conclusion:**

The conclusion drawn from the data included in this submission demonstrates that the changed device, HIT Clear Aligner system, does not alter the performance specification nor technological characteristics of the primary predicate device. The HIT Clear Aligner system is substantially equivalent to the predicate devices in indications for use, design, technological characteristics, mechanism of action, performance, materials, and biocompatibility. Intended use and performance are found to be substantially equivalent to the primary predicate device.