September 29, 2021

Inman Orthodontic Laboratories, Inc.
% Patsy Trisler
Regulatory Consultant
Trisler Consulting
7949 Beaumont Green East Drive
Indianapolis, Indiana 46250

Re: K210763
Trade/Device Name: Inman Digital Clear Aligners
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: NXC
Dated: August 30, 2021
Received: September 1, 2021

Dear Patsy Trisler:

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K210763

Device Name

Inman Digital Clear Aligners

Indications for Use *(Describe)*

Inman Digital Clear Aligners are indicated for the treatment of tooth malocclusions in patients with permanent dentition (i.e. all second molars). The Inman Digital Clear Aligners position 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 – K210763

Submitter Name:	Inman Orthodontic Laboratories, Inc.
Submitter Address:	3953 NW 126th Avenue Coral Springs, FL 33065
Phone Number:	800-289-0118
Contact Person:	Donal P Inman, President
Date Prepared:	September 21, 2021
Device Trade Name:	Inman Digital Clear Aligners
Common Name	Aligner, Sequential
Classification Name Number Product Code Regulatory Class	Orthodontic Plastic Bracket 21 CFR 872.5470 NXC 2
Primary Predicate Device:	K113618, ClearCorrect System, ClearCorrect, LLC
Reference Device	K152086, 3Shape OrthoSystem™, 3Shape A/S
Indications for Use	Inman Digital Clear Aligners are indicated for the treatment of tooth malocclusions in patients with permanent dentition (i.e. all second molars). The Inman Digital Clear Aligners position teeth by way of continuous gentle force.
Device Description, and Summary of Technological Characteristics	The Inman Digital Clear Aligners consist of a series of dental-clinician prescribed customized clear plastic removable orthodontic aligner trays that are made from a clear, thin thermoformed polyurethane. A dental clinician prescribes the aligners based on an evaluation of the patient's teeth. Either intraoral scans or physical impressions of the patient's teeth are provided to Inman Orthodontic Lab by the dental clinician, along with the prescription. The series of plastic aligner trays are designed according to the prescription using standard dental software for planning the tooth alignments. The software used is 3Shape Ortho System (Reference device K152086). It is used for managing 3D scanned orthodontic models, orthodontic diagnosis by measuring, analyzing, inspecting and visualizing 3D scanned orthodontic models, virtual planning of orthodontic treatments by simulating tooth movements and design of a variety of orthodontic appliances based on 3D scanned orthodontic models. After the plan is developed by Inman Orthodontic Lab, the prescribing dental clinician reviews and approves the model

scheme before the molds are produced. Following approval, the customized aligner trays are fabricated by Inman Orthodontic Lab by press thermoforming of the material on the molds using standard thermoforming equipment. The trays are provided to the dental clinician who provides them to the patient assuring fit and function during the entire treatment period.

Mechanism of Action

The aligners are designed to gradually move the patient's teeth incrementally, repositioning them from their original misaligned state to a more aligned state. This occurs through forces applied by the appliance to the teeth over time until final correction, according to the dental clinician's prescription, has been achieved.

Each aligner tray is worn by patients for approximately 22 hours per day for the prescribed period, until it is time to move to the next tray in the series.

Performance Testing

Laboratory Testing

Test data were submitted to:

- assure the mechanical properties of the aligner material meet specifications for up to 5 years shelf life [according to ASTM D638 standard's testing for: tensile strength (PSI), elongation (%), tensile@ yield (PSI), elongation @ yield (PSI) and tensile modulus (PSI)];
- assure the aligner material packaging retains the required moisture barrier properties;
- validate the processes used for the design and manufacture of the customized aligners, to ensure consistency between the aligner's digital design and the manufactured aligners.

All testing met the pre-determined acceptance criteria.

Biocompatibility

The thermoplastic polyurethane used for making the aligner series has been tested according to Good Laboratory Practices for its biocompatibility according to ISO 10993, as follows:

Part 3 (Bacterial Mutagenicity – Ames Assay),
Part 5 (Cytotoxicity Elution - MEM),
Part 10 (Intracutaneous/Intradermal Reactivity),
Part 10 (Oral Mucosa; Irritation),
Part 10 (Maximization for Delayed-Type Hypersensitivity),
Part 11 (Subacute Intraperitoneal Toxicity)

All testing showed that the material met the requirements of the test methods and is safe and biocompatible for the stated intended use.

Animal | Human Testing

Neither animal nor human testing are needed for this device because it is composed of the same materials, is designed similarly, and is manufactured by a similar method as the predicate device.

Comparison to Predicate Device:

There are no notable differences comparing the Inman Digital Clear Aligners to the predicate ClearCorrect aligner.

- The intended use is the same.
- The mechanism of action is similar.
- The polyurethane material used to make the aligners is the same.
- The method of manufacture for producing the customized clear aligners is similar.
- The use of software for planning and manufacturing are similar.

Substantial Equivalence Conclusion

Based on the documentation presented in the 510(k), as summarized above and illustrated in the following comparison table, it can be concluded that Inman Digital Clear Aligners medical device is substantially equivalent to the predicate device.

Substantial Equivalence Comparison

Trade Name:	Proposed: Inman Digital Clear Aligner	Predicate: ClearCorrect System
510(k) Number	TBC	K113618
Manufacturer	Inman Orthodontic Laboratory, Inc.	ClearCorrect, LLC
Classification # and Name Product Code Class	21 CFR 872.5470 Orthodontic Plastic Bracket NXC 2	21 CFR 872.5470 Orthodontic Plastic Bracket NXC 2
Indications for Use	Inman Digital Clear Aligners are indicated for the treatment of tooth malocclusions in patients with permanent dentition (i.e. all second molars). The Inman Digital Clear Aligners position teeth by way of continuous gentle force.	The ClearCorrect System indicated for the treatment of tooth malocclusions in patients with permanent dentition (i.e. all second molars). The ClearCorrect System positions teeth by way of continuous gentle force.
Mechanism of Action	Alignment of teeth by application of continuous gentle force, by sequential use of preformed plastic trays.	Alignment of teeth by application of continuous gentle force, by sequential use of preformed plastic trays.
Description of Use	Each preformed plastic tray is worn by the patient as prescribed by the dental practitioner, usually a few weeks prior to using the next sequential aligner tray.	Each preformed plastic tray is worn by the patient as prescribed by the dental practitioner, usually a few weeks prior to using the next sequential aligner tray.
Material	Thin thermoplastic polyurethane	Thin thermoplastic polyurethane
Manufacturing Method	Thermoforming	Thermoforming
Biocompatible	Yes, meets ISO 10993 requirements	Yes, meets ISO 10993 requirements
Prescription Use	Yes, Rx Only	Yes, Rx Only
Software Used for Treatment Planning / Manufacturing	Yes	Yes
Single Patient Use	Yes	Yes
Non-Sterile Packaging	Yes	Yes