



Digital Orthodontic Care
% Patsy Trisler
Regulatory Consultant
Trisler Consulting
5600 Wisconsin Avenue, #509
Chevy Chase, Maryland 20815

November 8, 2018

Re: K182329
Trade/Device Name: SureCure Orthodontic Aligner System
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: NXC
Dated: November 2, 2018
Received: November 2, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mary S.
Runner -S3

Digitally signed by
Mary S. Runner -S3
Date: 2018.11.08
08:47:46 -05'00'

For Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K182329

Device Name

SureCure Orthodontic Aligner System

Indications for Use (Describe)

The SureCure Orthodontic Aligner System is indicated for the treatment of tooth malocclusion in patients with permanent dentition. The 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.

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K182329

510(k) Summary

Submitter Name: Digital Orthodontic Care

Submitter Address: 348 Bronte Street, Unit 16
Milton, ON L9T 5B6 CANADA

Phone Number: 647-977-7253

Contact Person: Mr. Jeff Sheppard
President

Date Prepared: November 7, 2018

Device Trade Name: SureCure Orthodontic Aligner System

Common Name: Aligner, Sequential

Classification Name: Orthodontic Plastic Bracket
Number: 21 CFR 872.5470
Product Code: NXC
Regulatory Class: 2

Primary Predicate Device: K113618, ClearCorrect System, ClearCorrect, LLC

Reference Device: K152086, Ortho Analyzer, 3Shape A/S

Statement of Intended Use: The SureCure Orthodontic Aligner System is indicated for the treatment of tooth malocclusion in patients with permanent dentition. The aligner system repositions teeth by way of continuous gentle force.

Device Description and Summary of Technological Characteristics: Digital Orthodontic Care's SureCure Orthodontic Aligner System consists of a series of customized clear plastic removable aligners that are fabricated from a clear, thin thermoformed polyurethane. The aligners are designed to gradually move the patient's teeth incrementally, repositioning them from their original misalignment to a more aligned state.

Digital Orthodontic Care manufactures the customized aligners based on either standard impressions or intraoral scans sent to the company by the prescribing dentist or orthodontist. Digital Orthodontic Care manufactures models from the impressions and those models are scanned using standard validated software. The digital files are used to produce the aligner series with the thermoplastic polyurethane.

The thermoplastic material used for fabrication of the aligners is commonly used in many dental appliances, including the predicate aligners.

Mechanism of Action Based on the clinician’s treatment plan, each aligner is used for a defined period of time to exert gentle force to achieve progressive realignment of the teeth. This occurs over time until the final correction has been achieved.

Device Testing Laboratory Testing

Test data were submitted to validate the processes used for the design and manufacture of the aligners.

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. In addition, the final finished aligner device was tested according to ISO 10993, Part 5 (Cytotoxicity - MEM Elution).

The testing has shown that the material is safe and biocompatible for the stated intended use.

Shelf-life Testing

The aligner material has been tested after real-time storage for a shelf life of 5 years.

Animal | Human Testing

Neither animal nor human testing are required for this product 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: A side-by-side comparison of SureCure to the predicate device is presented in the Substantial Equivalence Comparison table.

Substantial Equivalence Conclusion Based on the documentation presented in the 510(k), as summarized above and in the following table, it can be concluded that Digital Orthodontic Care’s SureCure Orthodontic Aligner System is substantially equivalent to the predicate device.

Substantial Equivalence Comparison

Trade Name:	SureCure Orthodontic Aligner System	ClearCorrect System
510(k) Number	K182329	K113618
Manufacturer	Digital Orthodontic Care	ClearCorrect, LLC
Classification # & Product Code Class	21 CFR 852.5470 NXC 2	21 CFR 852.5470 NXC 2
Intended Use	The SureCure Orthodontic Aligner System is indicated for the treatment of tooth malocclusion in patients with permanent dentition. The aligner system repositions teeth by way of continuous gentle force.	The ClearCorrect System is indicated for the treatment of tooth malocclusion in patients with permanent dentition (i.e. all second molars). The Clear Correct System positions teeth by way of continuous gentle force.
Mode 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.
Method 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 thermoformed polyurethane	Thin thermoformed polyurethane
Method of Manufacture	Using software, molds/models are 3D printed based on the treatment plan. Aligners are fabricated on the molds using a thermoforming machine.	Using software, molds/models are 3D printed based on the treatment plan. Aligners are fabricated on the molds using a thermoforming machine.
Biocompatible	Yes	Yes
OTC or Rx	Rx	Rx
Software Use	Yes	Yes
Sterile	No	No