Great Lakes Orthodontics Ltd
Mr. David Graver
Director of Logistics
200 Cooper Ave
Tonawanda, New York 14150

June1, 2018

Re: K172765
Trade/Device Name: Smart Moves Complete
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: NXC
Dated: April 30, 2018
Received: May 2, 2018

Dear David Graver:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 -S

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172765

Device Name
Smart Moves Complete

Indications for Use *(Describe)*
Smart Moves Complete is indicated for the treatment of tooth malocclusion in patients with permanent dentition (i.e. all second molars). Smart Moves Complete 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.

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510(k) Summary

Smart Moves Complete

K172675

Sponsor

Great Lakes Orthodontics Ltd

200 Cooper Ave.

Tonawanda, NY 14150

Contact person:

Dave Graver

Director of Logistics

Date Prepared: May 31, 2018

Device Identification

Trade/Proprietary name: Smart Moves Complete

Regulation Number: 21CFR 872.5470

Regulation Name: Aligner Sequential/ Orthodontic Plastic Bracket

Panel: Dental

Product Class: II

Product Code: NXC

Legally Marketed Predicate Device

K113618, ClearCorrect System, ClearCorrect Inc.

Indications for Use

Smart Moves Complete is indicated for the treatment of tooth malocclusion in patients with permanent dentition (i.e. all second molars). Smart Moves Complete positions teeth by way of continuous gentle force.

Background

Orthodontic treatment is conventionally performed using brackets and archwires. A bracket is bonded to each tooth and a wire is inserted with the goal of moving each tooth to a desired final treatment position. An alternative to traditional bracket treatment has been in existence for the past 20 years. This alternative treatment uses clear plastic aligners to gradually move the teeth. The aligners are designed in a series of incremental stages. A patient wears each aligner stage for a period of two weeks to accomplish the programmed tooth movement. Once tooth movement has been accomplished for a given stage the current aligner is removed and the next aligner in the sequence is worn. This method of orthodontic treatment is popular with patients because it provides a virtually invisible appliance and avoids the appearance of braces on the teeth.

Design and Use

- This is a prescription use device by order of a Dentist or Orthodontist
- Designed for single patient use (2 weeks/aligner)
- Aligners are worn except for eating and brushing teeth. They are removed by the patient for those tasks.
- It is not provide sterile
- It does not contain any drugs or biologic
- Software as part of the system is used by the Dental lab to design the aligners that the Dental professional reviews and approves prior to fabrication.
- No clinical studies are included in the submission

Device Description

<u>Aligner System</u>

A dental health professional (e.g. orthodontist or dentist) prescribes Smart Moves Complete based on an assessment of the patient's teeth, takes molds of the patient's teeth, determines a course of treatment to reposition the teeth via gentle, corrective forces in the upper and lower dental arch, and completes a prescription form. Digital information concerning the patient's teeth and the prescription form are then sent electronically to Great Lakes Orthodontics.

Great Lakes then designs a series of plastic thermoformed aligners in a sequential series intended to gradually realign the patient's teeth in accordance with the physician's prescription using standard dental tooth alignment software. The prescribing physician accesses the doctor-facing portion of the standard dental tooth alignment software to review and approve the model scheme before the thermoformed aligners are produced. Once approved, Great Lakes Orthodontics produces these aligners, which are formed of clear, thin, thermoformed plastic.

The aligners in a sequential series are sent back to the dental health care professional who then provides them to the patient, confirming fit and design. Over a period of time, each progression of aligners are provided sequentially to the patient by the dental health professional to gradually move the target teeth to the designed position. The dental care professional monitors treatment from the moment the first aligner is delivered to when the final aligner is delivered. The aligners are held in place by pressure and can be removed by the patient at any time.

Predicate Device Comparison

Manufacturer	Great Lakes Orthodontics, Ltd.	ClearCorrect Inc.	Device Comparison
Trade Name	Smart Moves Complete	ClearCorrect System	N/A
510(k) Number	K172765	K113618	N/A
Product Code	NXC	NXC	Same
Regulation Number	872.5470	872.5470	Same
Regulation Name	Orthodontic Plastic Bracket	Orthodontic Plastic Bracket	Same
Indications for Use Statement	Smart Moves Complete is indicated for the treatment of tooth malocclusion in patients with permanent dentition (i.e. all second molars). Smart Moves Complete positions 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 ClearCorrect System positions teeth by way of continuous gentle force.	Same
Device Description	Smart Moves Complete consists of a series of doctor-prescribed, thin, clear plastic removable orthodontic appliances (aligners). The aligners gently move the patient's teeth in small increments from their original state to a more optimal, treated state. Smart Moves Complete is intended as an alternative to	The ClearCorrect device is fabricated of clear thin thermoformed polyurethane plastic in a sequential series to progressively reposition the teeth. Corrective force to straighten the teeth is delivered via minor changes into a position in each subsequent aligner.	Same; the device performs treatment of tooth malocclusions in the same way by continuous gentle force.

	conventional bracket technology and fixed appliances for the treatment of patients with malocclusion.		
Mode of Action	Orthodontic tooth movement occurs through forces applied by the appliance to the dentition as each tooth follows the programmed displacement based on a doctor's prescription.	Orthodontic tooth movement occurs through forces applied by the appliance to the dentition as each tooth follows the programmed displacement based on a doctor's prescription.	Same
Anatomy Location	Mouth; mucosal membranes	Mouth; mucosal membranes	Same
Size	Patient specific	Patient specific	Same
Manufacturing Method	Thermoforming	Thermoforming	Same
Material	0.03" Thermoplastic PETG	0.03" Thermoplastic Polyurethane	Similar; these are both thermoplastic forming materials that have same durometer, similar properties in modulus that do not raise any additional questions of safety or efficacy.
Biocompatibility	Passed ISO 10993-1 and series	Passed ISO 10993-1 and series	Same
Hardness Durometer	80 ± 3 Shore D	80 ± 3 Shore D	Same
Material Tensile Strength/Stress	Strength and stress of material tensile produced acceptable results for base material	Information not available	Base materials of thermoplastic used to fabricate aligners uses similar material used in these applications gentle tooth alignment. The materials are thermoformed plastics that are similar in composition to the predicate device not raising any additional questions of safety or efficacy.
Material Elongation	Elongation at yield and break produced acceptable results for base material	Information not available	Base materials of thermoplastic used to fabricate aligners uses similar material used in these applications gentle tooth alignment. The materials are thermoformed plastics that are similar in composition to the predicate device not raising any additional

			questions of safety or efficacy.
Material Modulus	Modulus results produced similar results for testing of base material	Information not available	Base materials of thermoplastic used to fabricate aligners uses similar material used in these applications gentle tooth alignment. The materials are thermoformed plastics that are similar in composition to the predicate device not raising any additional questions of safety or efficacy.
Material Load	Load at yield and break produced acceptable results for base material	Information not available	Base materials of thermoplastic used to fabricate aligners uses similar material used in these applications gentle tooth alignment. The materials are thermoformed plastics that are similar in composition to the predicate device not raising any additional questions of safety or efficacy.
Dental Tooth Alignment Software Description	The Smart Moves Complete 3-D software uses a scan of a PVS impression or a digital scan to generate the image of a final, treated state and then interprets a series of images that represent intermediate teeth states. Once the dental practitioner approves the treatment plan, the software converts the files to produce the series of patient specific aligners.	The standard dental tooth alignment software uses a scan of tooth impression or a digital scan to generate the image of a final, treated state and then interprets a series of images that represent intermediate teeth states. Once the dental practitioner approves the treatment plan, the software converts the files to produce the series of patient specific aligners.	Same
Healthcare Professional Review	The dental practitioner reviews final aligner series prior to fabrication and has the option to reject or request modifications to the set-up prior to approving it for aligner fabrication.	The dental practitioner reviews final aligner series prior to fabrication and has the option to reject or request modifications to the set-up prior to approving it for aligner fabrication.	Same

Non-Clinical Performance Testing

As part of demonstrating safety and effectiveness of Smart Moves Complete and in showing substantial equivalence to the predicate devices that are subject to this 510(k) submission, Great Lakes Orthodontics completed a number of non-clinical performance tests. The Smart Moves Complete meets all the requirements for overall design, biocompatibility, and performance results confirming that the design output meets the design inputs and specifications for the device.

The Smart Moves Complete passed all the testing in accordance with internal requirements, national standards, and international standards shown below to support substantial equivalence of the subject device:

- Biocompatibility testing per ISO 10993-1 passed cytotoxicity, sensitization, and irritation
- Software verification and validation testing using FDA's guidance document confirmed acceptance to required specifications
- There is no defined specification or standard for tensile strength so a sample of base materials used for fabrication of aligners were tested and analyzed producing acceptable results for tensile strength yield
- There is no defined specification or standard for aligner elongation which a sample of based materials used for fabrication of aligners were tested and analyzed showing acceptable results in comparison of break point
- There is no defined specification or standard for tensile stress so a sample of base materials used for fabrication of aligners were tested and analyzed producing acceptable results for tensile stress at break point
- There is no defined specification or standard for modulus so this was tested for the base materials used for fabrication of aligners to show acceptable results between the samples tested
- There is no defined specification or standard for load of materials which found acceptable results when tested and analyzed for samples of base material tested used for fabrication of aligners
- There is no defined specification or standard for water absorption which found acceptable results when tested and analyzed for fabricated aligners
- Durometer testing of thermoplastic forming material 80 ± 3 Shore D: Acceptable

- Process Flow validation was performed to ensure that the finished device matches the software output specifications. The output and work model and aligner were tested and compared. Aligners met the specifications of this testing.

Clinical Performance Data

There was no clinical testing performed to support the medical device as the indications for use is equivalent to the predicate device. The substantial equivalence is supported by non-clinical testing and the comparative table, so this is not required.

Substantial Equivalence Conclusion

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device. Based on the comparison and analysis above, the Smart Moves Complete is determined to be substantially equivalent to the referenced predicate device(s).