DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 24, 2016

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

Re: K150702
Trade/Device Name: eXceed Computerized Precision Bracket Placement Solution
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: II
Product Code: DYW, NJM, EJF
Dated: February 19, 2016
Received: February 23, 2016

Dear Mr. 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150702

Device Name
eXceed Computerized Precision Bracket Placement Solution

Indications for Use *(Describe)*
eXceed Computerized Precision Bracket Placement Solution is a software system intended for use as an aid in orthodontic treatment planning to correct Malocclusions in Orthodontic Patients. For use by dental professionals trained in orthodontic treatment, including radiographic analyses and treatment planning. eXceed Computerized Precision Bracket Placement Solution is intended for use with commercially available brackets currently used in standard orthodontic treatment. The end product is an indirect bonding tray for use by the Dental professional to place multiple brackets at the same time.

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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K150702
510K Summary

Submitter's name, address, phone, and contact person:

Great Lakes Orthodontics, Ltd. (Registration# 1316408)

200 Cooper Ave.

Tonawanda, NY 14150

Phone 716-319-1250 (direct)

Fax 716-871-0550

Contact person: Dave Graver

Email: dgraver@greatlakesortho.com

Date summary prepared: March 24, 2016

Trade / Proprietary Name of Device:

Exceed Computerized Precision Bracket Placement Solution

Common name of device:

Accessory to Orthodontic Brackets

Device classification name:

Orthodontic Plastic Bracket (Class II)

Classification regulation: 21CFR 872.5470

Product codes: DYW (Orthodontic plastic bracket), NJM (Orthodontic Ceramic Bracket), and ELF (Orthodontic Metal Bracket)

Predicate Device:

Ortho CAD iQ (510k # K082207}

Intended use/Indications for use

eXceed Computerized Precision Bracket Placement Solution is a software system intended for use as an aid in orthodontic treatment planning to correct Malocclusions in Orthodontic Patients. For use by dental professionals trained in orthodontic treatment, including radiographic analyses and treatment planning. eXceed Computerized Precision Bracket Placement Solution is intended for use with commercially available brackets currently used in standard orthodontic treatment. The end product is an indirect bonding tray for use by the Dental professional to place multiple brackets at the same time.

Technological Characteristics

The device consists of proprietary software that calculates the ideal position of the dental brackets based on the dental impressions and or 3D models supplied by the patients Orthodontist. Commercially available brackets are used as part of the system. A side by side comparison table is shown at the end of this summary.

Principals of operation

Using the images provided by the Dental Professional, the software creates a 3D model and identifies the ideal placement of the brackets. The file is sent to the Dental Professional for review and approval. The Dental Professional may adjust the final position of the bracket if desired. A 3D model is printed, and the brackets are placed on the model in the prescribed location, approved by the Orthodontist. An indirect bonding tray is fabricated with the brackets in place. The tray and brackets are sent to the Dental professional. The Dental Professional places the indirect tray using their chosen commercially available bracket adhesive.

While the subject and predicate devices do not have identical *Indications for Use* statements, they share the same intended use. Both are intended for use as aids in orthodontic treatment planning for use by dental professionals trained in orthodontic treatment, including radiographic analyses and treatment planning. Both are intended for use with commercially-available brackets.

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The operating principle for *Exceed Computerized Precision Bracket Placement Solution* and OrthoCAD iQ is identical, with the exception of the guidance method used by the technician in the manufacturing facility when pasting the brackets to the working model, prior to tray fabrication. The difference between the Subject and predicate devices is that the subject device employs a different guidance method for placing the brackets on the working model prior to trays' fabrication. *Exceed Computerized Precision Bracket Placement Solution* includes visual/physical frames on its models, while OrthoCAD provides virtual visual guidance only.

The difference in operating principle is minor, and does not render the subject device substantially different from the predicate device for the following reasons:

- The intended use of the different guidance method is the same as in the predicate device, providing the technician at the manufacturing facility clear and unequivocal guidance regarding where the brackets are to be placed on the working model, based on the approved placement plan.

- As confirmed in comparative testing, the visual guidance system used by the subject device is accurate, in the sense that it corresponds exactly with the virtual coordinates dictated by the approved placement plan, thus enabling the technician to place the brackets on the working model precisely according to that plan. As such, it is as safe and effective as the predicate and does not raise any new concerns.

Performance Data

The software is verified and validated by the digital model generated, matching the 3D model and bracket placement locations prescribed and approved by the Orthodontist.

Substantial Equivalence

Great Lakes Orthodontics Ltd has demonstrated that, for the purposes of FDA's regulation of medical devices, the *Exceed Computerized Precision Bracket Placement Solution* is substantially equivalent to the predicate device in terms of intended use, indications, technical characteristics, and principles of operation.

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Great Lakes Orthodontics, LTD.
An Employee Owned Company

Our Vision
"Delight our customers. Respect and Help our co-workers"

TECHNOLOGICAL CHARACTERISTICS
(Similarities & Differences)

	Exceed Computerized Precision Bracket Placement Solution	**Ortho CAD iQ**
Indications for Use	eXceed Computerized Precision Bracket Placement Solution is a software system intended for use as an aid in orthodontic treatment planning to correct Malocclusions in Orthodontic Patients. For use by dental professionals trained in orthodontic treatment, including radiographic analyses and treatment planning. eXceed Computerized Precision Bracket Placement Solution is intended for use with commercially available brackets currently used in standard orthodontic treatment. The end product is an indirect bonding tray for use by the Dental professional to place multiple brackets at the same time.	*Ortho CAD iQ* is a computer-guided system intended for use as an aid in orthodontic treatment planning for use by dental professionals trained in orthodontic treatment including radiographic analyses and treatment planning. *OrthoCAD iQ* is intended for use with commercially-available brackets and wires that apply continuous gentle force to reposition the teeth. It also uses indirect bonding trays to affix the brackets in position.
Key Records	A 3D model is generated from scanned analog impressions or directly from an intra-oral scan	A 3D model is generated from scanned analog impressions or directly from an intra-oral scan
Additional Records	A panoramic X-ray, facial and intra- oral images	A panoramic X-ray, facial and intra-oral images
Treatment Plan	A detailed treatment plan is provided by the clinician as part of case submission.	A detailed treatment plan is provided by the clinician as part of case submission.
Virtual Bracket Placement Plan	Using the submitted records and the prescribed treatment plan, a suggested placement plan is generated and sent for review by the clinician. The Clinician utilizes the eXceed software to adjust the plan and later have it approved.	Using the submitted records and the prescribed treatment plan, a suggested placement plan is generated and sent for review by the clinician. The Clinician utilizes the OrthoCAD software to adjust the plan and later have it approved.
Manufacturing	A working pre-treatment model, which includes tooth and bracket-specific landmarks depicting the position of the brackets based on the approved plan, is printed. Brackets are bonded by a technician within the landmarks.	A working pre-treatment model is printed. A technician bonds the brackets to the working model using a pen-like device for steering the appliances on the surface of the tooth and a computerized silhouette screened on the tooth depicting the approved bracket position.
Finished Product	Vacuum forming then follows to produce patient-specific bracket transfer trays.	Vacuum forming then follows to produce patient-specific bracket transfer trays.

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