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

November 18,2015

ALIGN TECHNOLOGY, INC.
Margaret Anderson,
Sr. Regulatory Affairs Analyst
2560 Orchard Parkway,
San Jose, CA 95131 US

Re: K143630
Trade/Device Name: Invisalign System
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic plastic bracket
Regulatory Class: Class II
Product Code: NXC
Dated: October 20, 2015
Received: October 21, 2015

Dear Ms. Anderson:

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 [**SELECT ONE:** Part 801 **[or, for IVDs only]** Parts 801 and 809**]**); 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" (21CFR 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,

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

**Indication for Use Statement**

**510(k) Number (if known):** K143630

**Device Name:** Invisalign System

**Indications for Use:**

The Invisalign System is indicated for the alignment of teeth during orthodontic treatment of malocclusion.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ___X____ OR Over-the Counter Use _____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

**K143630**
**510(k) Summary**

Date Prepared: November 18, 2015

**Applicant Information:**

Align Technology, Inc.
2560 Orchard Parkway
San Jose, CA 95131

Contact Person: Margaret Anderson
Phone Number: (408) 470-1410
Fax Number: (408) 470-1011

**Device Information:**

| | |
|---|---|
| Classification: | Class II |
| Trade Name: | Invisalign System |
| Common Name: | Aligner, Sequential |
| Classification Name: | Orthodontic plastic bracket (21 CFR 872.5470) |

**Device Description:**

The Invisalign System consists of a series of doctor-prescribed, thin, clear plastic removable orthodontic appliances (aligners) and proprietary 3-D software. The aligners gently move the patient's teeth in small increments from their original state to a more optimal, treated state. The Invisalign System is intended as an alternative to conventional wire/bracket technology and fixed appliances for the treatment of patients with malocclusion.

The proprietary Invisalign System 3-D software generates the image of a final, treated state and then interpolates a series of images that represent intermediate teeth states. The dental practitioner then reviews these images to depict, edit, view, monitor, and approve an orthodontic treatment plan. The dental practitioner has the option to reject or request modifications to the set-up prior to approving it for aligner fabrication. Once the doctor approves the set-up, the series of custom-made aligners are then manufactured, packaged, and shipped to the dental practitioner to be dispensed to the patient for treatment.

**Intended Use:**

The Invisalign System is indicated for the alignment of teeth during orthodontic treatment of malocclusion.

**Equivalent Device:**

The modified Invisalign System is substantially equivalent in intended use and/or method of operation to the Invisalign System (K081960). A comparison of the current and modified Invisalign System demonstrates that the device is substantially equivalent in terms of technology and performance characteristics.

| Characteristic | Invisalign System 3-D Software (K081960) Primary Predicate Device | Modified Invisalign System 3-D Software – (K143630) Subject Device | Comparison |
|---|---|---|---|
| **Intended Use Statement** | The Invisalign System is indicated for the alignment of teeth during orthodontic treatment of malocclusion. | The Invisalign System is indicated for the alignment of teeth during orthodontic treatment of malocclusion. | Subject Device is the same as predicate device. |
| **3-D Software Description** | The Align 3-D Software uses a scan of a PVS impression or a digital scan (which represents an untreated state) to generate the image of a final, treated state and then interprets a series of images that represent intermediate teeth states. The dental practitioner then reviews these images and has the option to reject or request modifications to the set-up prior to approving it for aligner fabrication. Once the dental practitioner approves the treatment plan, the software converts the files to produce the series of custom-made aligners. | The Align 3-D Software uses a scan of a PVS impression or a digital scan (which represents an untreated state) to generate the image of a final, treated state and then interprets a series of images that represent intermediate teeth states. The dental practitioner then reviews these images and has the option to reject or request modifications to the set-up prior to approving it for aligner fabrication. Once the dental practitioner approves the treatment plan, the software converts the files to produce the series of custom-made aligners | Subject Device is the same as predicate device. |
| **Mode of Operation for 3-D Software** | Invisalign system 3-D software performs the following operations:<br>• Produce 3D-model file of the PVS impression or digital scan.<br>• Identifies the individual teeth that will require treatment (i.e., repositioning).<br>• Creates a treatment plan (i.e., 3-D models that represent the treatment plan). The treating dental practitioner reviews these images using ClinCheck software and has the option to reject or request modifications to the set-up prior to approval. | Invisalign system 3-D software performs the following operations:<br>• Produce 3D-model file of the PVS impression or digital scan.<br>• Identifies the individual teeth that will require treatment (i.e., repositioning).<br>• Creates a treatment plan (i.e., 3-D models that represent the treatment plan). The treating dental practitioner reviews these images using ClinCheck software and has the option to reject or request modifications to the set-up prior to approval. | Subject Device is the same as predicate device. |
| **Elements of ClinCheck Software** | An electronic prescription form and process used to depict, edit, view, monitor and approve an orthodontic treatment plan. | An electronic prescription form and process used to depict, edit, view, monitor and approve an orthodontic treatment plan. | Subject Device is the same as predicate device. |
| **Elements of ClinCheck Software** | Treatment Plan File:<br>• The plan downloads to a dental practitioner's | Treatment Plan File:<br>• The plan downloads to other computing devices (e.g., | The Treatment Plan File is not downloaded and saved on |

| Characteristic | Invisalign System 3-D Software (K081960) Primary Predicate Device | Modified Invisalign System 3-D Software – (K143630) Subject Device | Comparison |
|---|---|---|---|
| **(continued)** | desktop/laptop computer<br>• The plan is stored on dental practitioner's desktop/laptop computer | tablets)<br>• The plan is deleted upon exiting application | desktop/laptop for K143630 as it is downloaded to a tablet and deleted upon exiting the application. |
| | Tool Bar and Buttons (e.g., Rotate/Translate, PAST, OCCLUS, View Attachment, Number, IPR, etc.) | Tool Bar and Buttons (e.g., Attachment, Number, IPR, etc.) | The following are not available on Subject Device tool Bar: Rotate/Translate, PAST, OCCLUS, and View |
| | Menu Bar (e.g., File, View, Export, Tools, Movie, Printing, Help, etc.) | Menu Bar (e.g., File, View, Export, Tools, Help, etc.) | Subject Device is same as predicate device, but without Movie and Printing |
| | Animation Controls (e.g., Display, Play/Stop, Step Forward, Step Backward, etc.) | Animation Controls: Play/Stop, Step Forward, and Step Backward | Subject Device controls are limited to: Play/Stop, Step Forward, and Step Backward |
| | Viewing options toolbar (e.g., grid, superimposition, basic buttons, etc.) | Viewing options toolbar (e.g., grid, superimposition, basic buttons, etc.) | Subject Device is equivalent to predicate device. |
| | Using text comments | Using text comments | Subject Device is equivalent to predicate device. |
| | 3-D modification mode (3-D Controls) | Absent | Not available in the Subject Device |
| | Advanced Software Features (e.g., Bolton Analysis, Movie generation and Screenshot generation, etc.) | Absent | Not available in the Subject Device |
| **Minimum Hardware Requirements** | • Intel® Core™ i5, 4 GB RAM, 2 GB free disk space; Graphics card: Intel HD Graphics; Windows 7, 32 bit; Internet Explorer 11, Chrome, Firefox, Edge | • iPad 2 with iOS 8 or higher; 16 GB storage or more<br>• Android 4.1.2 or higher; 16 GB storage or more | Subject Device is not used on a laptop/desktop computer as it operates on a tablet. |

The Indication for Use of the modified Invisalign System is the same as the currently marketed device. Also, as supported by the risk analysis and software testing, the minor difference between the modified Invisalign System and the currently marketed device (e.g., downloading ClinCheck to other computing devices) does not raise any new issues of safety and effectiveness. The ease-of-use, communication features that are not available in ClinCheck Mobile (e.g., 3D Controls, Bolton Analysis, Movie generation and Screenshot generation, etc.) can all be performed using text comments. Thus, the currently marketed, predicate device (K081960) and the modified Invisalign System are substantially equivalent.

**Test Results:**

Results of verification and validation testing demonstrate the Invisalign System showed conformity with pre-established specifications and acceptance criteria. The acceptance criteria were established in order to demonstrate the modified Invisalign System is substantially equivalent to the primary predicate device. Therefore, the results of this testing demonstrate the modified Invisalign System 3-D software is substantial equivalent to the primary predicate 3-D software. Software testing was conducted in accordance with "General Principles of Software Validation; Final Guidance for Industry and FDA Staff", 01/11/2002 and IEC 62304:2006 "Medical Device Software – Software Life-Cycle Processes".

**Conclusion:**

Based on the intended use and performance information provided in this notification, the modified Invisalign System has been shown to be substantially equivalent to the currently marketed predicate device.