DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Align Technology, Incorporated
881 Martin Avenue
Santa Clara, California 95050

MAR 2 0 2009

Re: K981095
Trade/Device Name: Align System
Regulation Number: 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: II
Product Code: NXC
Dated: July 30, 1998
Received: July 31, 1998

Dear Mr. Kolesar:

This letter corrects our substantially equivalent letter of September 8, 1998. We are issuing this letter solely because The Align System, as described in the indication for use, is equivalent to an orthodontic plastic bracket.

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 (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.

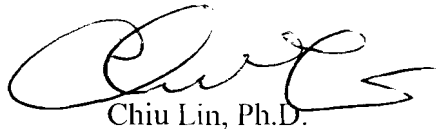
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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); 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.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: To Be Assigned By FDA K981095

Device Name: Align System

Indications For Use: The Align System is indicated for the treatment of tooth malocclusion in patients with permanent dentition (i.e., all second molars). The Align System positions teeth by way of continuous gentle force.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K981095

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

SEP 8 1998 K98 1095

SECTION 19: SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and CFR 807.92.

19.1 SUBMITTER INFORMATION

a.	Company Name:	Align Technology Inc.
b.	Company Address:	2991 El Camino Real, Suite 120 Redwood City, CA 94061
c.	Company Phone: Company Fax:	(650) 306-8912 (650) 306-8915
d.	Contact Person:	Kelsey Wirth President Align Technology Inc.
e.	Date Summary Prepared:	March 20, 1998

19.2. DEVICE IDENTIFICATION

a.	Trade/Proprietary Name:	Align System
b.	Classification Name:	Preformed Tooth Positioner (872.5525)

19.3 IDENTIFICATION OF PREDICATE DEVICE

Device	510(k) No.	Date Cleared
Great Lakes Orthodontics Preformed Tooth Positioner	Class I Exempt	Not Applicable
TP Orthodontics Tooth Positioner	K780619	June 28, 1978
Ortho-Tain Tooth Positioner	Class I Exempt	Not Applicable

19.4 DEVICE DESCRIPTION

Align Technology Inc. (Align) has developed the Align System, which is a series of clear plastic appliances (Aligners) that are intended to replace conventional wire and bracket technology for many orthodontic cases. The series of Aligners moves the patient's teeth in small increments from their original state to a final, treated state. The Align System will use a computer as a tool to assist in creating a series of Aligners that represent sequential movements to generate light and consistent forces on the patient's teeth.

A Dental Practitioner using the Align System diagnoses a patient, determines a treatment plan, and makes dental stone models of a patient's teeth. The Dental Practitioner then sends the molds, along with a prescription for treatment to Align. Align uses three-dimensional laser scanning technology to scan the mold into a computer. From this scanned image (which represents an untreated state) and following the Dental Practitioner's prescription, Align software generates the image of a final, treated state and then interpolates a series of images that represent intermediate teeth states. For each of these intermediate states, a rapid prototyping machine (such as a stereolithography machine) produces corresponding dental molds. In the final step, Align uses a conventional air pressure device (e.g., a Biostar) and commercially available retainer or positioner material (made by Raintree Essix or equivalent) to craft plastic Aligners to fit the developed teeth molds. The models with their corresponding Aligners are then mailed back to the Dental Practitioner. The total number of Aligners can vary from 1 to over 100 per patient, depending on the complexity of the case. The Aligners are individually identified and are dispensed to the patient by the Clinician with specific instructions for use (i.e., the Aligners are to be worn in a prescribed sequence).

19.5 SUBSTANTIAL EQUIVALENCE

The Align Technology Inc. Align System is of comparable type and is equivalent to the Preformed Tooth Positioners manufactured by Great Lakes Orthodontics, TP Orthodontics, and Ortho-Tain.

19.6 INTENDED USE

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

19.7 TECHNOLOGICAL CHARACTERISTICS

A comparison of the technological characteristics of the predicate and legally marketed devices has been performed. The results of this comparison demonstrate that the Aligners are equivalent to the currently marketed predicate devices.

19.8 PERFORMANCE DATA

Bench testing of the Aligners has not been performed due to the difficulty in evaluating this type of dental device in a laboratory setting. However, there is sufficient information available from the scientific literature to demonstrate that the preformed tooth positioner provides reasonable assurance of safety and effectiveness.

19.9 510(K) CHECKLIST

This notification contains all information required by 21 CFR 807.87. A completed copy of the Premarket Notification 510(k) Reviewer's Checklist has been provided with this submission.