ALIGN TECHNOLOGY INC
Form 8-K
February 28, 2006

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 8-K

CURRENT REPORT PURSUANT
TO SECTION 13 OR 15(D) OF THE
SECURITIES EXCHANGE ACT OF 1934

Date of report (Date of earliest event reported) February 28, 2006

ALIGN TECHNOLOGY, INC.
(Exact Name of Registrant as Specified in Its Charter)

Delaware		
(State or Other Jurisdiction of Incorporation)		
0-32259		94-3267295
(Commission File Number)		(IRS Employer Identification No.)
881 Martin Avenue, Santa Clara, California		95050
(Address of Principal Executive Offices)		(Zip Code)

(408) 470-1000
(Registrant's Telephone Number, Including Area Code)

Not applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

[ ] Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

[ ] Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

[ ] Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

[ ] Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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ITEM 8.01 OTHER EVENTS.

Align Technology, Inc. ("Align") has recently been informed by the FDA that its Invisalign(R) system, a proprietary method for treating the misalignment of teeth using a series of clear, removable aligners has been classified as a Class II medical device, correcting what the FDA described as a prior classification error. The Invisalign system was previously regulated as a Class I medical device and was exempted from requiring pre-market clearance by the FDA prior to commercial launch. In November 1998, however, Align voluntarily filed and subsequently received pre-market clearance by the FDA to market the Invisalign system. Class II devices typically require pre-market clearance by the FDA through the 510(k) pre-market notification process. As a result of this corrected classification, firms that now wish to market aligners for general use in the United States are required to obtain pre-market clearance from the FDA prior to commercialization.

Align currently possesses the necessary 510(k) clearance from the FDA to continue to market its product under the Class II classification. Prior to this classification correction, our product development, manufacturing processes, packaging, labeling, handling, storage and distribution activities were subject to extensive oversight by the FDA. Align believes its Invisalign system is in compliance in all material respects with applicable quality system regulations, record keeping and reporting requirements in the production and distribution of the Invisalign system. Align does not anticipate any significant difficulty or material cost increases in complying with applicable performance standards as a result of the incremental regulatory requirements resulting from the Class II classification.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: February 28, 2006

ALIGN TECHNOLOGY, INC.

By: /s/ Roger E. George

Roger E. George
Vice President,
Legal and Corporate Affairs,
General Counsel and Corporate Secretary