



FDA Clears Expanded Labeling for the Invisalign System

SANTA CLARA, Calif., Jan 12, 2009 /PRNewswire-FirstCall via COMTEX News Network/ --

Align Technology, Inc. (Nasdaq: ALGN) today announced that the U.S. Food and Drug Administration (FDA) has cleared new labeling for the Invisalign system, thereby removing the permanent dentition limitation from the indications for use. In addition, certain conditions previously listed as contraindications will now be listed as precautions.

"Over the years, our customers have demonstrated that many different types of malocclusion can be effectively treated with Invisalign," said Thomas M. Prescott, president and CEO. "Their clinical successes, along with our manufacturing and process improvements, have enabled us to amend our product labeling to reflect this broader applicability."

"Today, doctors are offering Invisalign primarily to adults and teens. This change is an important step towards facilitating our long term goal of making Invisalign the preferred orthodontic treatment option for patients of all ages and for more severe types of malocclusion," said Dr. Eric Kuo, vice president of clinical technology.

In 1998, the FDA cleared the Invisalign system for use in patients with permanent teeth and contraindicated the device for patients presenting with mixed dentition, severe overbite, severe overjet, tooth malocclusion requiring surgical correction, adolescent patients with a skeletally narrow jaw, and adult patients with dental prosthetics/implants. The recently cleared labeling change was made based on a better understanding of the broader applications of the Invisalign system, advances in Align's manufacturing capabilities, and advances in the current practice of orthodontic treatment being administered by doctors using the Invisalign system. For more information on the expanded labeling for the Invisalign system, please refer to Align's 510 (k) Premarket Notification located on the Company's investor relations section of its website: <http://investor.aligntech.com>.

About Align Technology, Inc.

Align Technology designs, manufactures and markets Invisalign, a proprietary method for treating malocclusion, or the misalignment of teeth. Invisalign corrects malocclusion using a series of clear, nearly invisible, removable appliances that gently move teeth to a desired final position. Because it does not rely on the use of metal or ceramic brackets and wires, Invisalign significantly reduces the aesthetic and other limitations associated with braces. Invisalign is appropriate for treating adults and teens. Align Technology was founded in March 1997 and received FDA clearance to market Invisalign in 1998. Today, the Invisalign product family includes Invisalign, Invisalign Teen, Invisalign Assist, Invisalign Express, and Vivera Retainers.

To learn more about Invisalign or to find an Invisalign-trained doctor in your area, please visit <http://www.invisalign.com> or call 1-800-INVISIBLE.

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