

Align Technology is a publicly traded medical device company engaged in the design, manufacture and marketing of the Invisalign® system, the world's leading invisible orthodontic product, and the iTero® Intraoral scanning systems and services. Align Technology went public on the NASDAQ market under the trading symbol ALGN in January 2001.

ALIGN TECHNOLOGY RECEIVES FDA 510(K) CLEARANCE FOR THE ITERO ELEMENT 5D IMAGING SYSTEM IN THE U.S.

March 24, 2020

Seeing is believing: imaging and visualization capabilities of the iTero Element 5D Imaging System are designed to enable better patient engagement and lead to increased patient acceptance of recommended dental treatment

- First intraoral scanner with near-infrared imaging (NIRI) technology that scans the internal structure of a tooth (enamel and dentin) in real time¹.
- First integrated dental imaging system that records 3D, intra-oral color and NIRI with a single scan, and enables comparison over time using iTero® TimeLapse¹.
- NIRI technology of the iTero Element® 5D system aids in detection and monitoring of interproximal caries lesions above the gingiva without using harmful radiation¹.

SAN JOSE, Calif., March 24, 2020 (GLOBE NEWSWIRE) -- Align Technology, Inc. (NASDAQ: ALGN) today announced that the U.S. Food and Drug Administration (FDA) has cleared the award winning iTero Element 5D Imaging System for commercial availability in the United States. The iTero Element 5D Imaging System expands the suite of existing high-precision, full-color imaging and fast scan times of the iTero Element intraoral scanner portfolio with a new clinical approach, optimized orthodontic and restorative dental workflows, and an improved doctor experience. In addition, iTero Element 5D Imaging System visualization tools improve patient engagement and communication by helping patients see and better understand their current dental health, their treatment plan options, and prescribed outcome on the iTero touchscreen, enabling better patient education, engagement, and compliance during treatment.

Commenting on today's announcement, Yuval Shaked, Align Technology senior vice president and managing director, iTero scanner and services business said, "The iTero Element 5D Imaging System seamlessly combines three key scanning technologies (3D data, intra-oral color photos and NIRI images) into one, integrated scan, and we are excited to bring this advancement in intraoral scanner technology to the U.S. market to help doctors provide better oral care for their patients. At the same time, we are mindful of the current environment and the impact that the COVID-19 pandemic is having across the world, and are focused solely on customer education regarding this new technology while so many dental practices in the U.S. are operating on a limited schedule."

iTero Element 5D Imaging System: better clinical care

The iTero Element 5D scanner is the first integrated dental imaging system that simultaneously records 3D, intra-oral color and NIRI images and enables comparison over time using iTero TimeLapse¹. Integrated 3D, intra-oral color and NIRI technology of the iTero Element 5D Imaging System aids doctors in detecting and monitoring the progression of interproximal caries (cavities or tooth decay) above the gingiva without using harmful radiation¹, thereby helping to ensure that their patients receive even better care with visualization, education, and treatment acceptance.

The diagnosis of carious lesions or "caries," especially interproximal lesions or those between teeth, can be hampered by several factors, including variations in the shape and alignment of teeth, traditional limitations of X-ray examinations that include variability in exposure level, bad angulations in the captured image, or overlapping contacts in the image, among other factors. With the iTero Element 5D Imaging System, doctors can scan patients at each visit to view a patient's progress over time and together view treatment options that result in clearer decisions for better clinical care.

A survey of doctors outside of the U.S. who had used the iTero Element 5D Imaging System for at least six months reported increases in interproximal caries detection, patient acceptance of treatment recommendations, and practice revenue.

More than just a scanner

With one full arch scan, completed in as little as 60 seconds², the iTero Element 5D Imaging System provides doctors with powerful visualization capabilities, including:

- NIRI (near infrared image)
- Intraoral camera
- 3D impressions for restorative and orthodontic work
- Analysis instruments, such as the Occlusogram occlusal clearance tool
- iTero TimeLapse technology
- Invisalign® Outcome Simulator and Progress Assessment

The U.S. Patent and Trademark Office has recently issued two patents that cover the advanced features in iTero Element 5D Imaging System: patent no. 10,390,913, entitled "Diagnostic Intraoral Scanning" and patent no. 10,507,087, entitled "Methods and Apparatuses for Forming a Three-Dimensional Volumetric Model of a Subject's Teeth." Additional patents covering other innovations in the iTero Element 5D Imaging System are pending.

The iTero Element 5D Imaging System will be commercially available in the United States in the second quarter of 2020 and is currently available in Canada, Latin America, European Union (EU) countries and EU EFTA countries, the United Kingdom, Australia, New Zealand, Hong Kong, Thailand, Japan, Korea, Singapore and Taiwan.

¹Data on file at Align Technology, as of December 4, 2018.

²Data on file at Align Technology, as of February 10, 2017.

Information about the iTero Element 5D Imaging System can be found at http://www.itero.com/en/products/itero_element_5d.

For a complete list of U.S. patents covering the iTero family of scanners see www.aligntech.com/patents.

About Align Technology, Inc.

Align Technology designs and manufactures the Invisalign® system, the most advanced clear aligner system in the world, and iTero® intraoral scanners and services. Align's products help dental professionals achieve the clinical results they expect and deliver effective, cutting-edge dental options to their patients. Visit www.aligntech.com for more information.

For additional information about the Invisalign system or to find an Invisalign doctor in your area, please visit www.invisalign.com.

For additional information about iTero digital scanning system, please visit www.itero.com.

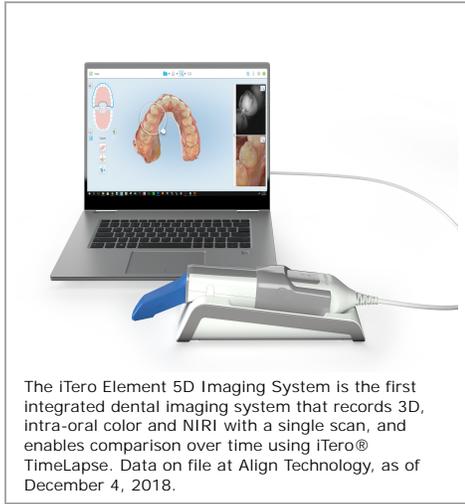
Forward Looking Statements

This press release contains forward-looking statements, including statements regarding the capabilities and performance of Align's products, the timing of their availability including as a result of the COVID-19 pandemic. These forward-looking statements are based on current expectations and estimates and involve a number of risks and uncertainties that could cause actual results to differ materially from those suggested by the forward-looking statements. These forward-looking statements should, therefore, be considered in light of various important factors, including, but not limited to the risk factors under the heading "Risk Factors" in the company's annual report on Form 10-K for the year ended December 31, 2019, as updated by the company's other filings with the Securities and Exchange Commission. Statements using words such as "estimates," "projects," "believes," "anticipates," "plans," "expects," "intends," "may," "will," "could," "should," "would," "targeted" and similar words and expressions are intended to identify forward-looking statements. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this press release. Align undertakes no obligation to publicly update or release any revisions to these forward-looking statements, except as required by law.

Photos accompanying this announcement are available at

<http://investor.aligntech.com/static-files/82ec9147-b66a-447d-97b7-6e035a978025>

<http://investor.aligntech.com/static-files/cb4f4eda-6408-49b5-8546-22b87450ba47>



The iTero Element 5D Imaging System is the first integrated dental imaging system that records 3D, intra-oral color and NIRI with a single scan, and enables comparison over time using iTero® TimeLapse. Data on file at Align Technology, as of December 4, 2018.



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Source: Align Technology, Inc.