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## 3Shape Ortho System Clear Aligner Workflow Receives FDA 510(k) Market Clearance

FDA market clearance means USA dental professionals can now use 3Shape Clear Aligner Studio software to produce clear aligners in-house

**Copenhagen, October 24, 2018** – 3Shape announces that the U.S. Food and Drug Administration (FDA) grants 510(k) USA market clearance for the 3Shape Ortho System clear aligner workflow.

The 3Shape Ortho System clear aligner workflow is used in 3Shape’s Clear Aligner Studio software. Because of this, USA dental professionals can now use 3Shape Clear Aligner Studio to design and produce their own orthodontic clear aligner treatments.

3Shape Clear Aligner Studio guides professionals through the case analysis, setup and staging, and export to print for production.

Using simple and intuitive workflows, the software provides analysis of arch shapes, overjet/overbite, Bolton ratios, occlusion and spaces. From there, virtual setups can be created and subdivided into the clear aligner stages needed. Attachments and interproximal reduction can also be added to the treatment plan and when planning is complete, sub-setups can be prepared for printing. Production files can be exported for 3D printing and vacuum forming. The software is compatible with a wide range of 3D printers.

“Around the world, hundreds of thousands of clear aligners are produced every year using 3Shape Clear Aligner Studio. It is very exciting that USA professionals now have the same opportunity to take total control of their design, budgeting and production of clear aligners,” says Allan Hyldal, Vice President of 3Shape Orthodontics.

Like all 3Shape solutions, 3Shape Clear Aligner Studio is open. Professionals are free to decide how much of the workflow they want to do inhouse and/or seamlessly send to design and production partners.

Because the workflow is digital, treatment planning and simulations can be shared onscreen with patients as well as between practice and lab via the 3Shape Communicate cloud platform.

### **About 3Shape**

3Shape is changing dentistry together with dental professionals across the world by developing innovations that provide superior dental care for patients. Our portfolio of 3D scanners and CAD/CAM software solutions includes the multiple award-winning 3Shape TRIOS intraoral scanner, the upcoming 3Shape X1 CBCT scanner, as well as market-leading scanning and design software solutions for both dental practices and labs.

Two graduate students founded 3Shape in Denmark’s capital in the year 2000. Today, 3Shape has over 1,400 employees serving customers in over 100 countries from an ever-growing number of 3Shape offices around the world. 3Shape’s

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products and innovations continue to challenge traditional methods, enabling dental professionals to treat more patients more effectively. [www.3shape.com](http://www.3shape.com)



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