

*For Immediate Release*

Contact: Bruce Frederic Mendel, 3Shape Communications  
E-mail: [bruce.mendel@3shape.com](mailto:bruce.mendel@3shape.com)  
Web: [www.3shape.com](http://www.3shape.com)  
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## 3Shape Ortho System receives FDA 510(k) market clearance *FDA clearance now covers design of dental retainers, splints, nightguards and mouthguards*

**Copenhagen, April 21, 2017** – 3Shape announces that the U.S. Food and Drug Administration (FDA) has granted 510(k) USA market clearance for additional indications in 3Shape Ortho System™ software for orthodontics.

3Shape Ortho System enables orthodontic professionals to overlay DICOM, cephalometric, and 2D pictures along with intraoral scans for orthodontic case analysis and planning, treatment simulations and the design of FDA-cleared orthodontic appliances.

The FDA now extends Ortho System's 510(k) market clearance to include the design of dental retainers, splints, mouthguards and nightguards in addition to previously cleared indications: custom metal bands, export models, and indirect direct bonding transfer media.

3Shape will present the solution at its press conference at the American Association of Orthodontists meeting in San Diego (AAO 2017), April 22, 10:00AM – booth #3519.

Professionals use 3Shape Ortho System coupled with 3Shape scanners to create digital study models. Digital study models provide a space and cost saving alternative to traditional analog gypsum models.

Because the software enables professionals to work digitally, they are able to share treatment planning and simulations onscreen with patients as well as seamlessly collaborate between clinic, lab, and 3<sup>rd</sup> party orthodontic solution providers via the 3Shape Communicate cloud platform.

This FDA market clearance also includes 3Shape Indirect Bonding and transfer media solutions, as well as several appliance design workflows that guide the user through the design phase and relevant production parameter settings.

“The new FDA clearance for Ortho System now gives US orthodontic practices and lab owners even more options when using the most comprehensive, versatile and easy-to-use orthodontic solution on the market,” says Allan Hyldal, Vice President of 3Shape Orthodontics.

For orthodontists wanting to learn more about 3Shape Ortho System, please go to,

<http://www.3shape.com/discover/orthodontist>

For orthodontic labs wanting to learn more about 3Shape Ortho System, please go to,

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<http://www.3shape.com/discover/orthodontic+lab>

## **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 for the dental industry includes the multiple award-winning 3Shape TRIOS intraoral scanner, the game-changing 3Shape X1 4-in-1 CBCT scanner, and market-leading scanning and design software solutions for dental labs. Two graduate students founded 3Shape in the year 2000, and today the company's fast-growing team of employees in 19 offices worldwide is serving customers in over 100 countries. 3Shape's products and innovations continue to challenge traditional methods, enabling dental professionals to treat more people more effectively. [www.3shape.com](http://www.3shape.com).

