



3Shape Receives FDA 510(k) Clearance for 3Shape Dx Software



Copenhagen, April 27, 2026 - 3Shape today announced that the U.S. Food and Drug Administration (FDA) has granted FDA clearance for its Dx Software following a review completed on April 10, 2026.

The 510(k) Premarket Notification allows Dx (R1) software to be commercially available in the United States for use by qualified dental professionals in dental clinics to aid in the diagnosis of key oral health conditions and the assessment of changes in teeth and gingiva in adult patients.

“I’m excited that we can now bring this transformative dental solution to doctors and patients across the United States,” says 3Shape CEO Jacob Paulsen. “Receiving FDA 510(k) clearance for Dx underscores our commitment to responsible innovation and to delivering digital solutions that meet the highest clinical and regulatory standards. With Dx software, dental professionals gain a powerful new way to communicate more clearly with patients about their oral health and treatment needs.”

The FDA clearance applies to both versions of 3Shape’s Dx software: Dx Plus and Dx Standard. Exclusively compatible with 3Shape TRIOS 6 scans, **Dx Plus** is an AI-assistive software that aids in the detection of key oral health conditions, including surface and proximal caries, plaque, tooth wear, and gingival recession. The **Dx Standard** software can help dentists engage patients by manually tracking and quantifying changes to their dentition. It is compatible with all 3Shape TRIOS models except TRIOS Core.

Dx supports routine checkups and can save time when preparing for a patient’s visit. Using Dx, dentists can visualize key oral health conditions with their patients onscreen and monitor them over time. Dx Plus visualizations turn clinical findings into clear, intuitive visuals that help patients better understand their diagnosis, build trust with their clinician, and feel more confident in recommended treatment plans.

The FDA clearance means that Dx software can now be marketed and sold to dental professionals in the U.S. Since 2025, the Dx software has been sold and used by clinicians across multiple international markets, including Europe, the Middle East, Africa, South America, and Canada.

3Shape's Dx software is available in the U.S. starting today. Please contact your reseller or 3Shape representative for purchase information. Eligible customers can go to webshop.3shape.com to start a trial.

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About 3Shape

3Shape is a global innovator in digital dentistry, empowering dental professionals to provide superior dental care for every patient, every time. Its award-winning digital solutions advance and connect practices and labs. Founded in Denmark in 2000, 3Shape employs more than 2,200 dedicated professionals, who together serve customers in 100+ countries. Private equity fund EQT has been a shareholder since 2021. For more information, visit www.3shape.com.