

# InformAI Receives 510(k) FDA Clearance for Radiation Therapy Dose Planning Software

*AI-powered SaMD streamlines radiation therapy dose planning for head & neck cancers*



HOUSTON, TX, UNITED STATES, July 15, 2026 /EINPresswire.com/ -- [InformAI, Inc.](#), a leader in innovative medical

technology, is proud to announce that it has received 510(k) approval from the U.S. Food and Drug Administration (FDA) to market an AI-enabled radiation therapy dose planning software, [RadOncAI™](#). This clinician co-pilot software-as-a-medical-device uses artificial intelligence (AI) to optimize the key step in radiation dose planning for head & neck cancer patients.



This clearance represents a major step forward in our mission to bring innovative and clinically impactful solutions to the healthcare industry."

*Jim Havelka*

RadOncAI enables AI-driven radiation therapy, generating an optimized radiation dose plan that targets tumors while minimizing radiation exposure to adjacent healthy tissues. This milestone marks a significant advancement in the development and availability of the InformAI portfolio of AI healthcare applications. With this FDA clearance, the product has met rigorous safety and efficacy standards, demonstrating its ability to deliver meaningful benefits to healthcare providers and patients. The development effort

of this product involved clinical research testing on a patient cohort of over 900 patients.

This clearance allows InformAI to market and distribute the product in the United States.

"We are thrilled to receive 510(k) clearance for RadOncAI," said CEO and Founder Jim Havelka.

"This clearance represents a major step forward in our mission to bring innovative and clinically impactful solutions to the healthcare industry. We believe RadOncAI will assist radiation oncologists in generating quality dose plans more efficiently."

The RadOncAI product involves InformAI proprietary IP as well as licensed IP from the University of Texas Southwestern Medical Center (UTSW). InformAI also acknowledges the Cancer Prevention and Research Initiative of Texas ([CPRIT](#)) for funding the DP220063 grant, which supports the RadOncAI product

development.

#### About InformAI

InformAI is a technology company dedicated to advancing healthcare through AI-enabled clinical solutions. We specialize in creating sophisticated products for oncology and diagnostic imaging to improve patient outcomes. InformAI was founded with the belief that AI can provide a paradigm shift in healthcare by using predictive analytics to assist clinicians in diagnosing medical conditions and improving patient treatment plans.

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