

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

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

HOUSTON, TX, UNITED STATES, July 16, 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 [RadOncAI™](#), an AI-enabled software for radiation therapy dose planning. This clinician co-pilot software-as-a-medical-device uses artificial intelligence (AI) to optimize the key step in radiation therapy dose planning for head & neck cancer patients.



InformAI is based in Houston's Texas Medical Center.

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This clearance marks a major step toward our mission to deliver innovative, clinically impactful solutions. RadOncAI will help radiation oncologists generate high-quality dose plans more efficiently.”

Jim Havelka

RadOncAI enables AI-driven radiation therapy, generating an optimized treatment dose plan that targets tumors while minimizing exposure to adjacent healthy tissues. RadOncAI demonstrated the ability to assist clinicians in delivering optimized, clinically achievable dose plans in a fraction of the time required by existing clinical processes, resulting in substantial clinical productivity and cost savings. 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 for this product involved clinical research testing on a cohort of more than 900 cancer patients. This regulatory clearance allows InformAI to market and distribute both cloud- and on-premise-hosted RadOncAI products in the United States.

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

“This clearance marks a major step toward our mission to deliver innovative, clinically impactful

solutions to the healthcare industry. We believe RadOncAI will help radiation oncologists generate high-quality dose plans more efficiently and provide the software platform for additional planned cancer indications.”

Each year, approximately 1 million cancer patients in the United States receive radiation therapy.

InformAI acknowledges the Cancer Prevention and Research Initiative of Texas ([CPRIT](#)) for funding the DP220063 grant, which supports RadOncAI product development.

About InformAI

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

Jackie Coleman
InformAI, Inc.
jcoleman@informai.com

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