FOR IMMEDIATE RELEASE
December 2, 2024

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RadUnity Solution Receives FDA 510(k) Clearance as a Class II Medical Device

Madison, Wisconsin – RadUnity Corp., a University of Wisconsin-Madison (UW) spin-off, has received FDA 510(k) clearance as a Class II Medical Device for its innovative healthcare solution. This marks a major milestone in the company's mission to ensure consistent formatting and image presentation in computed tomography (CT) scans.

Led by founder Timothy Szczykutowicz, PhD, RadUnity developed a stand-alone software application that allows centralized protocol specification, management, standardization, and networking of CT images. In collaboration with Innolitics and the Asher-Orion Group LLC, the company rigorously validated its minimum viable product (MVP), which has now been FDA-cleared. Being a practitioner-founded company, it was important that the RadUnity validation plan included clinical validation by board-certified radiologists and accredited CT technologists.

"With this clearance, we've made a significant leap toward turning an academic concept into a practical clinical solution. This milestone will help us secure additional funding and expand our team. It brings us closer to fulfilling my goal of providing a solution that the community will embrace and use to improve patient care," said Founder Tim Szczykutowicz.

For more on RadUnity, please visit https://radunity.com/

About RadUnity:
RadUnity Corp. is a start-up using technology developed at UW Madison based on IP owned by the Wisconsin Alumni Research Foundation (WARF) and invented by its founder, Tim "Stick" Szczykutowicz. RadUnity is a platform that presents harmonized images from diverse Computer Tomography (CT) data tailored for any radiologist, researcher, or AI tool. Our vision is to become a standard building block of any institution's medical imaging informatics system, providing a platform of harmonization services to satisfy the needs of radiologists and the AI vendors that assist them.