

Cubresa Announces FDA 510(k) Clearance for the Cubresa BrainPET™ Scanner, Opening New Frontier in Clinical Brain Imaging

WINNIPEG, MANITOBA, CANADA, August 20, 2026 /EINPresswire.com/ -- [Cubresa](#) Inc., a global leader in clinical and preclinical molecular imaging technologies, today announced that it has received FDA 510(k) clearance from the U.S. Food and Drug Administration (FDA) for its groundbreaking [Cubresa BrainPET™](#) scanner.



CUBRESA
Leaders in Brain Imaging

The Cubresa BrainPET™ is an innovative, dedicated Positron Emission Tomography (PET) scanner designed to retrofit seamlessly into existing Siemens Biograph mMR MR/PET devices. This allows medical institutions to perform simultaneous, high-resolution PET/MR brain imaging without the massive capital expense of buying a standalone, whole-body hybrid system.

"FDA 510(k) clearance is a transformative milestone for Cubresa, bringing our world-class brain imaging technology directly into frontline clinical settings," said James Schellenberg, PhD, Founder and CEO of Cubresa. "By enabling simultaneous molecular and anatomical scanning on existing MRI infrastructure, we are empowering clinicians to better evaluate, diagnose, and manage complex neurological conditions including Alzheimer's disease and other dementias, epilepsy, and brain cancers."

A Paradigm Shift in Neuroimaging Performance & Accessibility

Traditional whole-body PET/MR scanners are cost-prohibitive and require extensive, dedicated space. Cubresa's BrainPET changes the paradigm with a low-profile design at a much lower price point. The Cubresa BrainPET™ scanner delivers excellent image quality when simultaneous PET/MRI of the brain is needed but can be removed to enable whole-body MRI imaging when required. The Cubresa BrainPET is a powerful tool for clinical sites looking to expand their brain imaging capabilities.

About Cubresa Inc.

Cubresa is a world leader in the design and development of clinical and preclinical PET inserts for MRI. Cubresa's products enable medical professionals at leading universities, hospitals, and pharmaceutical companies to visualize and measure biochemical processes at the molecular

level, advancing precision medicine in neuroscience, oncology, and psychiatry. For more information, visit www.cubresa.com.

Lisa Bako

Cubresa Inc

+1 204-798-4579

[email us here](#)

Visit us on social media:

[LinkedIn](#)

This press release can be viewed online at: <https://www.einpresswire.com/article/935756252>

EIN Presswire's priority is source transparency. We do not allow opaque clients, and our editors try to be careful about weeding out false and misleading content. As a user, if you see something we have missed, please do bring it to our attention. Your help is welcome. EIN Presswire, Everyone's Internet News Presswire™, tries to define some of the boundaries that are reasonable in today's world. Please see our Editorial Guidelines for more information.

© 1995-2026 Newsmatics Inc. All Right Reserved.