

K253963 Cubresa BrainPET

Jul 17, 2026
218 days to decision

K253963 · Product code: **OUO** · Radiology
Source: <https://www.510kdatabase.net/k253963/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tomographic Imager Combining Emission Computed Tomography With Nuclear Magnetic Resonance (OUO)
Date received	Dec 11, 2025
Decision date	Jul 17, 2026
Days to decision	218 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cubresa, Inc.
Location	Winnipeg, CA
Contact	Lisa Bako
510(k) history	1 submissions · 1 cleared · 2026-2026