

K243881 HeartSee™ Cardiac P.E.T. Processing Software For Myocardial Perfusion and Coronary Flow Reserve (CFR) Version 4Mar 3, 2025
75 days to decisionK243881 · Product code: **KPS** · Radiology
Source: <https://www.510kdatabase.net/k243881/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Tomography, Computed, Emission (KPS)
Date received	Dec 18, 2024
Decision date	Mar 3, 2025
Days to decision	75 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Bracco Diagnostics, Inc.
Location	Monroe Township, NE, US
Contact	Elyssa Murray
510(k) history	2 submissions · 2 cleared · 2018-2025

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