

K182716 Brain Perfusion (BP) applicationMay 29, 2019
244 days to decisionK182716 · Product code: **JAK** · Radiology
Source: <https://www.510kdatabase.net/k182716/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomography, Computed (JAK)
Date received	Sep 27, 2018
Decision date	May 29, 2019
Days to decision	244 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Philips Medical Systems Nederland B.V.
Location	Best, NL
Contact	Yoram Levy
510(k) history	103 submissions · 102 cleared · 2005-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k182716/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 15, 2026