

K201573 Brain Perfusion (BP) applicationAug 17, 2021
432 days to decisionK201573 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k201573/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Jun 11, 2020
Decision date	Aug 17, 2021
Days to decision	432 days
Third-party review	No
Combination product	No
PCCP authorized	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

REGULATORY CONSULTANT

Consulting firm	Qsite
Contact	Yoram Levy

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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