

K201583 SmartCT R1.0Feb 9, 2021
243 days to decisionK201583 · Product code: **OWB** · Radiology
Source: <https://www.510kdatabase.net/k201583/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	Jun 11, 2020
Decision date	Feb 9, 2021
Days to decision	243 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	Maria Silos Viu
510(k) history	103 submissions · 102 cleared · 2005-2026

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