

K201743 ClarifEye R1.0, ClarifEye NeedleFeb 23, 2021
243 days to decisionK201743 · Product code: **OWB** · Radiology
Source: <https://www.510kdatabase.net/k201743/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	Jun 25, 2020
Decision date	Feb 23, 2021
Days to decision	243 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Philips Medical Systems Nederlands B.V.
Location	Best, NL
Contact	Owen Callaghan
510(k) history	8 submissions · 8 cleared · 2015-2024

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