

K213479 D²RS and D²RS 9090Dec 23, 2021
55 days to decisionK213479 · Product code: **OWB** · Radiology
Source: <https://www.510kdatabase.net/k213479/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	Oct 29, 2021
Decision date	Dec 23, 2021
Days to decision	55 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Stephanix
Location	La Ricamarie, FR
Contact	Sandie Perret
510(k) history	3 submissions · 3 cleared · 2021-2022

REGULATORY CONSULTANT

Consulting firm	Kamm & Associates
Contact	Daniel Kamm

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

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