

**K221335 D<sup>2</sup>RS and D<sup>2</sup>RS 9090**Jun 7, 2022  
29 days to decisionK221335 · Product code: **OWB** · Radiology  
Source: <https://www.510kdatabase.net/k221335/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	May 9, 2022
Decision date	Jun 7, 2022
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Kamm &amp; Associates</b>
Contact	Daniel Kamm

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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