FDA 510(k) Premarket Notification

# K213479 D²RS and D²RS 9090

**CLEARED**

Dec 23, 2021
55 days to decision

K213479 · Product code: **OWB** · Radiology
Source: https://www.510kdatabase.net/k213479/

## SUBMISSION DETAILS

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|---|---|
| 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

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|---|---|
| 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