FDA 510(k) Premarket Notification

K221335 D²RS and D²RS 9090

CLEARED

Jun 7, 2022
29 days to decision

K221335 · Product code: **OWB** · Radiology
Source: https://www.510kdatabase.net/k221335/

SUBMISSION DETAILS

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

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