FDA 510(k) Premarket Notification

K213455 ControlRad Select Model Z

CLEARED

Nov 24, 2021
29 days to decision

K213455 · Product code: **OWB** · Radiology
Source: https://www.510kdatabase.net/k213455/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	Oct 26, 2021
Decision date	Nov 24, 2021
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Controlrad, Inc.**
Location	Radnor, PA, US
Contact	Chris Fair
510(k) history	6 submissions · 6 cleared · 2019-2021

REGULATORY CONSULTANT

Consulting firm	**Secure BioMed Evaluations**
Contact	Patricia Jones

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k213455/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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