

**K211782 ControlRad Select Model Z, ControlRad Trace Model 8,
ControlRad Trace Model 9**Jul 1, 2021
22 days to decisionK211782 · Product code: **OWB** · Radiology
Source: <https://www.510kdatabase.net/k211782/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	Jun 9, 2021
Decision date	Jul 1, 2021
Days to decision	22 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	Linda Braddon

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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