

**K183109 ControlRad Trace Model 8**May 13, 2019  
186 days to decisionK183109 · Product code: **OWB** · Radiology  
Source: <https://www.510kdatabase.net/k183109/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	Nov 8, 2018
Decision date	May 13, 2019
Days to decision	186 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Controlrad, Inc.</b>
Location	Radnor, PA, US
Contact	Guillaume Bailliard
510(k) history	6 submissions · 6 cleared · 2019-2021

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k183109/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 26, 2026