

**K200360 TrackX**Mar 5, 2020  
21 days to decisionK200360 · Product code: **OWB** · Radiology  
Source: <https://www.510kdatabase.net/k200360/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	Feb 13, 2020
Decision date	Mar 5, 2020
Days to decision	21 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Track X Technology, LLC</b>
Location	Durham, NC, US
Contact	David Skwerer
510(k) history	2 submissions · 2 cleared · 2018-2020

**REGULATORY CONSULTANT**

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Consulting firm	<b>Biologics Consulting</b>
Contact	Calley Herzog

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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