

K173736 TrackXFeb 28, 2018
84 days to decisionK173736 · Product code: **OWB** · Radiology
Source: <https://www.510kdatabase.net/k173736/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	Dec 6, 2017
Decision date	Feb 28, 2018
Days to decision	84 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Track X Technology, LLC
Location	Durham, NC, US
Contact	Calley Herzog
510(k) history	2 submissions · 2 cleared · 2018-2020

REGULATORY CONSULTANT

Consulting firm	Biologics Consulting Group, Inc.
Contact	Calley Herzog

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

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