

K250010 EXTRON 3Jun 10, 2025
159 days to decisionK250010 · Product code: **OWB** · Radiology
Source: <https://www.510kdatabase.net/k250010/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	Jan 2, 2025
Decision date	Jun 10, 2025
Days to decision	159 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	EXTRON 5; EXTRON 7

APPLICANT

Company	DRTECH Corporation
Location	Seongam-Si, KR
Contact	Minjeong Kim
510(k) history	25 submissions · 25 cleared · 2015-2025

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