

K212159 Shield SystemMar 30, 2022
261 days to decisionK212159 · Product code: **OWB** · Radiology
Source: <https://www.510kdatabase.net/k212159/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	Jul 12, 2021
Decision date	Mar 30, 2022
Days to decision	261 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Radiation , Ltd.
Location	Tel Aviv, IL
Contact	Jonathan Yifat
510(k) history	2 submissions · 2 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	Sfadc, LLC
Contact	Susan Alpert

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

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