

K222998 F3Jun 20, 2023
265 days to decisionK222998 · Product code: **OWB** · Radiology
Source: <https://www.510kdatabase.net/k222998/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	Sep 28, 2022
Decision date	Jun 20, 2023
Days to decision	265 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Acrew Imaging, Inc.
Location	Ocean View, DE, US
Contact	Craig Hughes
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	Yolanda Smith
Contact	Yolanda Smith

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

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