

**K212336 Soteria.AI**Nov 17, 2021  
113 days to decisionK212336 · Product code: **OWB** · Radiology  
Source: <https://www.510kdatabase.net/k212336/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	Jul 27, 2021
Decision date	Nov 17, 2021
Days to decision	113 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Omega Medical Imaging, LLC</b>
Location	Sanford, FL, US
Contact	John Newman
510(k) history	7 submissions · 7 cleared · 2012-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k212336/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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