

K242488 Soteria E-ViewJan 6, 2025
138 days to decisionK242488 · Product code: **JAA** · Radiology
Source: <https://www.510kdatabase.net/k242488/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Fluoroscopic, Image-intensified (JAA)
Date received	Aug 21, 2024
Decision date	Jan 6, 2025
Days to decision	138 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Omega Medical Imaging, LLC
Location	Sanford, FL, US
Contact	Matthew Anderson
510(k) history	7 submissions · 7 cleared · 2012-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k242488/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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