

**K100102 CS-SERIES-FP**Aug 31, 2010  
230 days to decisionK100102 · Product code: **OWB** · Radiology  
Source: <https://www.510kdatabase.net/k100102/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	Jan 13, 2010
Decision date	Aug 31, 2010
Days to decision	230 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Omega Medical Imaging, Inc.</b>
Location	Sanford, FL, US
Contact	James Princehorn
510(k) history	8 submissions · 8 cleared · 1990-2010

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