

K070834 CS-SERIES FLUOROSCOPY SYSTEM, CS-10 THROUGH CS-65 (11 CONFIGURATIONS)

May 18, 2007
52 days to decision

K070834 · Product code: **OWB** · Radiology
Source: <https://www.510kdatabase.net/k070834/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	Mar 27, 2007
Decision date	May 18, 2007
Days to decision	52 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Omega Medical Imaging, Inc.
Location	Sanford, FL, US
Contact	JAMES A PRINCEHORN
510(k) history	8 submissions · 8 cleared · 1990-2010

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Device record: <https://www.510kdatabase.net/k070834/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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