

K082781 OEC 9900 ELITEMay 1, 2009
221 days to decisionK082781 · Product code: **OWB** · Radiology
Source: <https://www.510kdatabase.net/k082781/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	Sep 22, 2008
Decision date	May 1, 2009
Days to decision	221 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ge Healthcare Surgery
Location	Salt Lake City, UT, US
Contact	MARIA C FRAME
510(k) history	1 submissions · 1 cleared · 2009-2009

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