K061953 9900 PLUS MOBILE FLUOROSCOPY SYSTEM WITH 3D AND NAVIGATION OPTIONS

CLEARED

Aug 15, 2006
36 days to decision

K061953 · Product code: **OWB** · Radiology
Source: https://www.510kdatabase.net/k061953/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	Jul 10, 2006
Decision date	Aug 15, 2006
Days to decision	36 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Ge Oec Medical Systems**
Location	Salt Lake City, UT, US
Contact	GREG HANSEN
510(k) history	7 submissions · 7 cleared · 2001-2008