

K092564 O-ARM IMAGING SYSTEMJun 17, 2010
301 days to decisionK092564 · Product code: **OXO** · Radiology
Source: <https://www.510kdatabase.net/k092564/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Image-intensified Fluoroscopic X-ray System, Mobile (OXO)
Date received	Aug 20, 2009
Decision date	Jun 17, 2010
Days to decision	301 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Medtronic Navigation, Inc. (Littleton)
Location	Littleton, MA, US
Contact	SETH KUZDZAL
510(k) history	1 submissions · 1 cleared · 2010-2010

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k092564/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026