

K093066 I5 DIGITAL X-RAY IMAGING SYSTEM, MODEL I5Mar 16, 2010
167 days to decisionK093066 · Product code: **OWB** · Radiology
Source: <https://www.510kdatabase.net/k093066/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	Sep 30, 2009
Decision date	Mar 16, 2010
Days to decision	167 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Infimed, Inc.
Location	Liverpool, NY, US
Contact	JIGAR SHAH
510(k) history	14 submissions · 14 cleared · 1993-2011

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k093066/> 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 17, 2026