

K022114 IMPERIUMSep 17, 2002
81 days to decisionK022114 · Product code: **OWB** · Radiology
Source: <https://www.510kdatabase.net/k022114/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	Jun 28, 2002
Decision date	Sep 17, 2002
Days to decision	81 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Elmstech, Inc.
Location	Westbury, NY, US
Contact	TIM MANGERUGA
510(k) history	1 submissions · 1 cleared · 2002-2002

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k022114/> 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 19, 2026