

K012490 ORION DIGITAL IMAGING SYSTEMFeb 12, 2002
193 days to decisionK012490 · Product code: **OWB** · Radiology
Source: <https://www.510kdatabase.net/k012490/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Interventional Fluoroscopic X-ray System (OWB)
Date received	Aug 3, 2001
Decision date	Feb 12, 2002
Days to decision	193 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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