

K950630 WALLACH DIGITAL IMAGING SYSTEMNov 22, 1995
282 days to decisionK950630 · Product code: **LMB** · Radiology
Source: <https://www.510kdatabase.net/k950630/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Digital Image Storage, Radiological (LMB)
Date received	Feb 13, 1995
Decision date	Nov 22, 1995
Days to decision	282 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Wallach Surgical Devices, Inc.
Location	Walker, MI, US
Contact	RAYMOND A WILEY
510(k) history	27 submissions · 27 cleared · 1981-2002

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k950630/> 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 20, 2026