

K973028 HELIOS LASER IMAGER 1417Oct 28, 1997
75 days to decisionK973028 · Product code: **LMC** · Radiology
Source: <https://www.510kdatabase.net/k973028/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Camera, Multi Format, Radiological (LMC)
Date received	Aug 14, 1997
Decision date	Oct 28, 1997
Days to decision	75 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sterling Diagnostic Imaging, Inc.
Location	Newark, DE, US
Contact	TIMOTHY W CAPEHART
510(k) history	7 submissions · 7 cleared · 1996-1998

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k973028/> 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