FDA 510(k) Premarket Notification

K973028 HELIOS LASER IMAGER 1417

CLEARED

Oct 28, 1997
75 days to decision

K973028 · 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