FDA 510(k) Premarket Notification

K933409 IMPAX 1000

CLEARED

Nov 3, 1993
114 days to decision

K933409 · Product code: **LMD** · Radiology
Source: https://www.510kdatabase.net/k933409/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Digital Image Communications, Radiological (LMD)
Date received	Jul 12, 1993
Decision date	Nov 3, 1993
Days to decision	114 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Heraeus Kulzer, Inc.**
Location	Elkhart, IN, US
Contact	MICHAEL SULLIVAN
510(k) history	145 submissions · 145 cleared · 1988-2009