

K933409 IMPAX 1000Nov 3, 1993
114 days to decisionK933409 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k933409/> 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