

**K934386 IMPAX 5000**Jan 5, 1994  
119 days to decisionK934386 · Product code: **LMD** · Radiology  
Source: <https://www.510kdatabase.net/k934386/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Digital Image Communications, Radiological (LMD)
Date received	Sep 8, 1993
Decision date	Jan 5, 1994
Days to decision	119 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k934386/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 20, 2026