

K080612 LEICA FL800May 9, 2008
66 days to decisionK080612 · Product code: **IZI** · Radiology
Source: <https://www.510kdatabase.net/k080612/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Angiographic (IZI)
Date received	Mar 4, 2008
Decision date	May 9, 2008
Days to decision	66 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Leica Microsystems (Schweiz) AG
Location	Orange, CA, US
Contact	COLLEEN BOSWELL
510(k) history	4 submissions · 2 cleared · 2008-2019

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k080612/> 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 June 19, 2026