FDA 510(k) Premarket Notification

K080612 LEICA FL800

CLEARED

May 9, 2008
66 days to decision

K080612 · 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