FDA 510(k) Premarket Notification

K170239 Leica FL560

CLEARED

Jul 5, 2017
160 days to decision

K170239 · Product code: **IZI** · Radiology
Source: https://www.510kdatabase.net/k170239/

SUBMISSION DETAILS

Decision	Substantially Equivalent - KD
Submission type	Traditional
Device classification	System, X-ray, Angiographic (IZI)
Date received	Jan 26, 2017
Decision date	Jul 5, 2017
Days to decision	160 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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