FDA 510(k) Premarket Notification

K181537 GLOW800

CLEARED

Sep 7, 2018
88 days to decision

K181537 · Product code: **IZI** · Neurology
Source: https://www.510kdatabase.net/k181537/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Angiographic (IZI)
Date received	Jun 11, 2018
Decision date	Sep 7, 2018
Days to decision	88 days
Third-party review	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k181537/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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