FDA 510(k) Premarket Notification

K113063 CT-GUIDE NEEDLE GUIDANCE SYSTEM

CLEARED

Nov 10, 2011
27 days to decision

K113063 · Product code: **JAK** · Radiology
Source: https://www.510kdatabase.net/k113063/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, X-ray, Tomography, Computed (JAK)
Date received	Oct 14, 2011
Decision date	Nov 10, 2011
Days to decision	27 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Activiews, Ltd.**
Location	Washington, Dc, DC, US
Contact	JOHN J SMITH
510(k) history	3 submissions · 3 cleared · 2011-2012

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k113063/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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