FDA 510(k) Premarket Notification

K091673 GE LIGHTSPEED ACT FP16

CLEARED

Jun 24, 2009
15 days to decision

K091673 · Product code: **JAK** · Radiology
Source: https://www.510kdatabase.net/k091673/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomography, Computed (JAK)
Date received	Jun 9, 2009
Decision date	Jun 24, 2009
Days to decision	15 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	**Ge Medical Systems, Inc.**
Location	Milwaukee, WI, US
Contact	ALLEN SCHUH
510(k) history	54 submissions · 54 cleared · 1997-2009