FDA 510(k) Premarket Notification

K093234 INTEGRATED REGISTRATION

CLEARED

Oct 30, 2009
15 days to decision

K093234 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k093234/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Oct 15, 2009
Decision date	Oct 30, 2009
Days to decision	15 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	**GE Medical Systems SCS**
Location	Buc Cedex, FR
Contact	SOPHIE LE LOARER
510(k) history	37 submissions · 37 cleared · 2008-2026

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k093234/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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