FDA 510(k) Premarket Notification

K121827 GSI VIEWER WITH VUE OPTION

CLEARED

Sep 13, 2012
84 days to decision

K121827 · Product code: **JAK** · Radiology
Source: https://www.510kdatabase.net/k121827/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomography, Computed (JAK)
Date received	Jun 21, 2012
Decision date	Sep 13, 2012
Days to decision	84 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k121827/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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