FDA 510(k) Premarket Notification

K964746 HISPEED CT/I WITH PERFORMIX TUBE AND WARP SCAN OPTION

CLEARED

Jan 24, 1997
59 days to decision

K964746 · Product code: **JAK** · Radiology
Source: https://www.510kdatabase.net/k964746/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomography, Computed (JAK)
Date received	Nov 26, 1996
Decision date	Jan 24, 1997
Days to decision	59 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**GE Medical Systems**
Location	Milwaukee, WI, US
Contact	LARRY A KROGER
510(k) history	169 submissions · 166 cleared · 1989-2022