FDA 510(k) Premarket Notification

K941546 SOMATOM PROJECT 059

CLEARED

Sep 20, 1994
173 days to decision

K941546 · Product code: **JAK** · Radiology
Source: https://www.510kdatabase.net/k941546/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomography, Computed (JAK)
Date received	Mar 31, 1994
Decision date	Sep 20, 1994
Days to decision	173 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Siemens Corp.**
Location	Mchenry, IL, US
Contact	CATHY A PINTO
Website	http://www.siemens.it/
510(k) history	66 submissions · 66 cleared · 1978-2010

Siemens Corp. is a global technology company headquartered in McHenry, US. The company develops medical imaging and diagnostic equipment for healthcare providers worldwide. Siemens has received FDA 510(k) clearances from total submissions. The company's regulatory focus centers on Radiology devices, which represent the dominant category of its cleared portfolio. FDA 510(k) clearances span from 1978 to 2010, establishing a significant historical record in medical device regulation. Recent cleared devices include advanced imaging systems such as CT scanners, MR systems, X-r...