

**K982536 PERFUSION CT (COMPUTED TOMOGRAPHY)
SOFTWARE PACKAGE**Nov 24, 1998
126 days to decisionK982536 · Product code: **JAK** · Radiology
Source: <https://www.510kdatabase.net/k982536/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomography, Computed (JAK)
Date received	Jul 21, 1998
Decision date	Nov 24, 1998
Days to decision	126 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Siemens Corp.
Location	Mchenry, IL, US
Contact	MALGORZATA STANEK
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...