FDA 510(k) Premarket Notification

K790975 SOMATOM 2

CLEARED

Jul 30, 1979
68 days to decision

K790975 · Product code: **JAK** · Radiology
Source: https://www.510kdatabase.net/k790975/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Tomography, Computed (JAK)
Date received	May 23, 1979
Decision date	Jul 30, 1979
Days to decision	68 days
Third-party review	No

APPLICANT

Company	**Siemens Corp.**
Location	Mchenry, IL, US
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...