FDA 510(k) Premarket Notification

K781992 KOORDINAT ANGIO

CLEARED

Dec 7, 1978
13 days to decision

K781992 · Product code: **KXJ** · Radiology
Source: https://www.510kdatabase.net/k781992/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Table, Radiologic (KXJ)
Date received	Nov 24, 1978
Decision date	Dec 7, 1978
Days to decision	13 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...