FDA 510(k) Premarket Notification

# K991600 SOMATOM PLUS 4 WITH SLIDING GANTRY OPTION

**CLEARED**

Jun 9, 1999
30 days to decision

K991600 · Product code: **JAK** · Radiology
Source: https://www.510kdatabase.net/k991600/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | System, X-ray, Tomography, Computed (JAK) |
| Date received | May 10, 1999 |
| Decision date | Jun 9, 1999 |
| Days to decision | 30 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Siemens Corp.** |
| Location | Mchenry, IL, US |
| Contact | ALICIA BUSTOS-JUERGENSEN |
| 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...