FDA 510(k) Premarket Notification

K802200 VERTIX 3D-U

CLEARED

Oct 23, 1980
42 days to decision

K802200 · Product code: **KPR** · Radiology
Source: https://www.510kdatabase.net/k802200/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Stationary (KPR)
Date received	Sep 11, 1980
Decision date	Oct 23, 1980
Days to decision	42 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...