FDA 510(k) Premarket Notification

K810190 OPTI 110/12/50HSG

CLEARED

Mar 2, 1981
38 days to decision

K810190 · Product code: **ITY** · Radiology
Source: https://www.510kdatabase.net/k810190/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assembly, Tube Housing, X-ray, Diagnostic (ITY)
Date received	Jan 23, 1981
Decision date	Mar 2, 1981
Days to decision	38 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...