FDA 510(k) Premarket Notification

K812610 SIEMENS-ELEMA PULSE GENERATOR 668 B

CLEARED

Dec 10, 1981
86 days to decision

K812610 · Product code: **DXY** · Cardiovascular
Source: https://www.510kdatabase.net/k812610/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Implantable Pacemaker Pulse-generator (DXY)
Date received	Sep 15, 1981
Decision date	Dec 10, 1981
Days to decision	86 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...