

K812104 SIEMENS-ELEMA PSA 376Dec 2, 1981
131 days to decisionK812104 · Product code: **DTA** · Cardiovascular
Source: <https://www.510kdatabase.net/k812104/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tester, Pacemaker Electrode Function (DTA)
Date received	Jul 24, 1981
Decision date	Dec 2, 1981
Days to decision	131 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...

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