

**K812721 DIGITRON**Nov 4, 1981  
37 days to decisionK812721 · Product code: IZI · Radiology  
Source: <https://www.510kdatabase.net/k812721/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Angiographic (IZI)
Date received	Sep 28, 1981
Decision date	Nov 4, 1981
Days to decision	37 days
Third-party review	No

**APPLICANT**

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Company	<b>Siemens Corp.</b>
Location	Mchenry, IL, US
Website	<a href="http://www.siemens.it/">http://www.siemens.it/</a>
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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