

K984224 PERFUSION PACKAGE FOR MAGNETOM VISION AND SYMPHONY SYSTEMSFeb 2, 1999
69 days to decisionK984224 · Product code: LNH · Radiology
Source: <https://www.510kdatabase.net/k984224/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Nuclear Magnetic Resonance Imaging (LNH)
Date received	Nov 25, 1998
Decision date	Feb 2, 1999
Days to decision	69 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Siemens Corp.
Location	Mchenry, IL, US
Contact	KATHLEEN RUTHERFORD
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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Device record: <https://www.510kdatabase.net/k984224/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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