FDA 510(k) Premarket Notification

K984221 FUNCTIONAL MRI PACKAGE FOR MAGETETOM VISION MR

CLEARED

Feb 12, 1999
79 days to decision

K984221 · Product code: **LNH** · Radiology
Source: https://www.510kdatabase.net/k984221/

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 12, 1999
Days to decision	79 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...