FDA 510(k) Premarket Notification

CLEARED

K162102 MAGNETOM Avantofit, MAGNETOM Skyrafit

Nov 22, 2016
116 days to decision

K162102 · Product code: **LNH** · Radiology
Source: https://www.510kdatabase.net/k162102/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Nuclear Magnetic Resonance Imaging (LNH)
Date received	Jul 29, 2016
Decision date	Nov 22, 2016
Days to decision	116 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Siemens Medi Cal Solutions, Inc.**
Location	Ann Arbor, MI, US
Contact	JOHN URTZ
510(k) history	32 submissions · 32 cleared · 2004-2020