FDA 510(k) Premarket Notification

K002105 SIEMENS INFINITY SC 6002XL ENHANCED WITH ST SEGMENT ANALYSIS

CLEARED

Dec 5, 2000
146 days to decision

K002105 · Product code: **MLD** · Cardiovascular
Source: https://www.510kdatabase.net/k002105/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, St Segment With Alarm (MLD)
Date received	Jul 12, 2000
Decision date	Dec 5, 2000
Days to decision	146 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Siemens Medical Solutions USA, Inc.**
Location	Hoffman Estates, IL, US
Contact	PENELOPE H GRECO
510(k) history	778 submissions · 778 cleared · 1980-2026