FDA 510(k) Premarket Notification

K012016 INFINITY SC 8000 WITH ADVANCED COMMUNICATION OPTION II

CLEARED

Jul 20, 2001
22 days to decision

K012016 · Product code: **MHX** · Cardiovascular
Source: https://www.510kdatabase.net/k012016/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Monitor, Physiological, Patient(with Arrhythmia Detection Or Alarms) (MHX)
Date received	Jun 28, 2001
Decision date	Jul 20, 2001
Days to decision	22 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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k012016/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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