FDA 510(k) Premarket Notification

K030129 MODIFICATION TO ENSITE 3000 SYSTEM, MODEL EE3000

CLEARED

Apr 22, 2003
98 days to decision

K030129 · Product code: **DQK** · Cardiovascular
Source: https://www.510kdatabase.net/k030129/

SUBMISSION DETAILS

Decision	Substantially Equivalent - U
Submission type	Traditional
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Jan 14, 2003
Decision date	Apr 22, 2003
Days to decision	98 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Endocardial Solutions, Inc.**
Location	St. Paul, MN, US
Contact	KAREN J MCKELVEY
510(k) history	8 submissions · 4 cleared · 1999-2004

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k030129/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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