FDA 510(k) Premarket Notification

K033211 ENSITE SYSTEM

CLEARED

Oct 30, 2003
27 days to decision

K033211 · Product code: **DQK** · Cardiovascular
Source: https://www.510kdatabase.net/k033211/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Oct 3, 2003
Decision date	Oct 30, 2003
Days to decision	27 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