FDA 510(k) Premarket Notification

K992479 ENSITE 3000 SYSTEM

CLEARED

Dec 2, 1999
129 days to decision

K992479 · Product code: **DQK** · Cardiovascular
Source: https://www.510kdatabase.net/k992479/

SUBMISSION DETAILS

Decision	Substantially Equivalent - U
Submission type	Traditional
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Jul 26, 1999
Decision date	Dec 2, 1999
Days to decision	129 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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