

K983456 ENSITE 3000 SYSTEMApr 21, 1999
203 days to decisionK983456 · Product code: **MTD** · Cardiovascular
Source: <https://www.510kdatabase.net/k983456/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - U
Submission type	Traditional
Device classification	Catheter, Intracardiac Mapping, High-density Array (MTD)
Date received	Sep 30, 1998
Decision date	Apr 21, 1999
Days to decision	203 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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