

**K012926 MODIFICATION TO ENSITE 3000 SYSTEM, MODEL EE3000**Sep 28, 2001  
28 days to decisionK012926 · Product code: **MTD** · Cardiovascular  
Source: <https://www.510kdatabase.net/k012926/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent - U
Submission type	Special
Device classification	Catheter, Intracardiac Mapping, High-density Array (MTD)
Date received	Aug 31, 2001
Decision date	Sep 28, 2001
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Endocardial Solutions, Inc.</b>
Location	St. Paul, MN, US
Contact	ERIC W KOEHLER
510(k) history	8 submissions · 4 cleared · 1999-2004

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k012926/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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