

K001437 ENSITE 3000 SYSTEM, MODEL EE3000Jun 7, 2000
30 days to decisionK001437 · Product code: **DQK** · Cardiovascular
Source: <https://www.510kdatabase.net/k001437/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Computer, Diagnostic, Programmable (DQK) |
| Date received | May 8, 2000 |
| Decision date | Jun 7, 2000 |
| Days to decision | 30 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

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

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