

**K101419 ENSITE VELOCITY SYSTEM, MODEL EE3000**Jun 11, 2010  
22 days to decisionK101419 · Product code: **DQK** · Cardiovascular  
Source: <https://www.510kdatabase.net/k101419/>**SUBMISSION DETAILS**

---

|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)       |
| Submission type       | Special                                  |
| Device classification | Computer, Diagnostic, Programmable (DQK) |
| Date received         | May 20, 2010                             |
| Decision date         | Jun 11, 2010                             |
| Days to decision      | 22 days                                  |
| Third-party review    | No                                       |
| Summary / Statement   | Summary                                  |

**APPLICANT**

---

|                |   |
|----------------|---|
| Company        | <b>St Jude Medical</b>                                |
| Location       | Minnetonka, MN, US                                    |
| Contact        | DONNA R LUNAK   |
| Website        | <a href="http://www.sjm.com/">http://www.sjm.com/</a> |
| 510(k) history | 105 submissions · 105 cleared · 2000-2018             |

St Jude Medical was a global medical device company headquartered in Little Canada, Minnesota. The company operated more than 20 principal facilities worldwide and sold products in over 100 countries. St Jude Medical received FDA 510(k) clearances from total submissions between 2000 and 2018. The company's regulatory focus centered on Cardiovascular devices, which represented 91% of all submissions. Notable cleared products include cardiac mapping systems, pacing catheters, and mobile cardiac applications. Now part of Abbott Laboratories following its acquisition in Janua...

---