

**K081258 VARIABLE LASSO NAV CATHETER, MODELS:  
D-1290-01, D-1290-02**Jan 6, 2009  
249 days to decisionK081258 · Product code: **DRF** · Cardiovascular  
Source: <https://www.510kdatabase.net/k081258/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)                                 |
| Submission type       | Traditional  |
| Device classification | Catheter, Electrode Recording, Or Probe, Electrode Recording (DRF) |
| Date received         | May 2, 2008  |
| Decision date         | Jan 6, 2009  |
| Days to decision      | 249 days   |
| Third-party review    | No   |
| Summary / Statement   | Summary  |

**APPLICANT**

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|----------------|---|
| Company        | <b>Biosense Webster, Inc.</b>                                       |
| Location       | Irvine, CA, US  |
| Contact        | NATALIE BENNINGTON  |
| Website        | <a href="https://www.jnjmedtech.com">https://www.jnjmedtech.com</a> |
| 510(k) history | 73 submissions · 73 cleared · 1999-2026                             |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k081258/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 23, 2026