

**K140466 PRESSUREWIRE: AERIS AGILE TIP, AERIS AGILE TIP  
300, CERTUS AGILE TIP, CERTUS AGILE TIP 300**Nov 13, 2014  
262 days to decisionK140466 · Product code: **DXO** · Cardiovascular  
Source: <https://www.510kdatabase.net/k140466/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)       |
| Submission type       | Traditional                              |
| Device classification | Transducer, Pressure, Catheter Tip (DXO) |
| Date received         | Feb 24, 2014                             |
| Decision date         | Nov 13, 2014                             |
| Days to decision      | 262 days                                 |
| Third-party review    | No                                       |
| Summary / Statement   | Summary                                  |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>St. Jude Medical Systems AB</b>    |
| Location       | Uppsala, SE                           |
| Contact        | Jeffrey Roberts                       |
| 510(k) history | 5 submissions · 5 cleared · 2011-2014 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k140466/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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