

**K062769 PRESSUREWIRE CERTUS, MODELS 12006 AND 12306**Dec 4, 2006  
80 days to decisionK062769 · Product code: **DXO** · CardiovascularSource: <https://www.510kdatabase.net/k062769/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Transducer, Pressure, Catheter Tip (DXO)
Date received	Sep 15, 2006
Decision date	Dec 4, 2006
Days to decision	80 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Radi Medical Systems AB</b>
Location	Uppsala, SE
Contact	MATS GRANLUND
510(k) history	24 submissions · 24 cleared · 1990-2013

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k062769/> 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 May 21, 2026