

**K080813 PRESSUREWIRE CERTUS, CERTUS (300CM), AERIS,
AERIS (300CM), RECEIVER**Jul 1, 2008
102 days to decisionK080813 · Product code: **DXO** · Cardiovascular
Source: <https://www.510kdatabase.net/k080813/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transducer, Pressure, Catheter Tip (DXO)
Date received	Mar 21, 2008
Decision date	Jul 1, 2008
Days to decision	102 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Radi Medical Systems AB
Location	Uppsala, SE
Contact	BJORN PALMGREN
510(k) history	24 submissions · 24 cleared · 1990-2013

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k080813/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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