

K042628 MODIFICATION TO: RADIANALYZER, MODEL 12711Jan 19, 2005
114 days to decisionK042628 · Product code: **DQK** · Cardiovascular
Source: <https://www.510kdatabase.net/k042628/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Computer, Diagnostic, Programmable (DQK)
Date received	Sep 27, 2004
Decision date	Jan 19, 2005
Days to decision	114 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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