

K132691 ABL90 FLEXNov 13, 2014
442 days to decisionK132691 · Product code: **MQM** · Chemistry
Source: <https://www.510kdatabase.net/k132691/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bilirubin (total And Unbound) In The Neonate Test System (MQM)
Date received	Aug 28, 2013
Decision date	Nov 13, 2014
Days to decision	442 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Radiometer Medical Aps
Location	Bronshoj, DK
Contact	SOREN BOGESTRAND
510(k) history	28 submissions · 28 cleared · 2004-2017

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