

K170882 ABL90 FLEX, ABL90 FLEX PLUSApr 28, 2017
35 days to decisionK170882 · Product code: **MQM** · Chemistry
Source: <https://www.510kdatabase.net/k170882/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bilirubin (total And Unbound) In The Neonate Test System (MQM)
Date received	Mar 24, 2017
Decision date	Apr 28, 2017
Days to decision	35 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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