

**K130415 HIGH METABOLITE QUALICHECK**Mar 26, 2013  
35 days to decisionK130415 · Product code: **JJS** · Chemistry  
Source: <https://www.510kdatabase.net/k130415/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Controls For Blood-gases, (assayed And Unassayed) (JJS)
Date received	Feb 19, 2013
Decision date	Mar 26, 2013
Days to decision	35 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Radiometer Medical Aps</b>
Location	Bronshoj, DK
Contact	Martin Gabler
510(k) history	28 submissions · 28 cleared · 2004-2017

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k130415/> 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 24, 2026