

**K012040 RAMP MYOGLOBIN ASSAY**Dec 18, 2001  
172 days to decisionK012040 · Product code: **DDR** · Chemistry  
Source: <https://www.510kdatabase.net/k012040/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Myoglobin, Antigen, Antiserum, Control (DDR)
Date received	Jun 29, 2001
Decision date	Dec 18, 2001
Days to decision	172 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Response Biomedical Corp.</b>
Location	Burnaby, British Columbia, CA
Contact	WILLIAM J RADVAK
510(k) history	7 submissions · 7 cleared · 2001-2009

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k012040/> 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 June 22, 2026