

**K151482 BCR-30-min BI™ and RBIP-ST30™ Readout Accessory**Feb 26, 2016  
269 days to decisionK151482 · Product code: **FRC** · General Hospital  
Source: <https://www.510kdatabase.net/k151482/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Indicator, Biological Sterilization Process (FRC)
Date received	Jun 2, 2015
Decision date	Feb 26, 2016
Days to decision	269 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Bcr Diagnostics, Inc.</b>
Location	Phoenix, AZ, US
Contact	BORIS ROTMAN
510(k) history	1 submissions · 1 cleared · 2016-2016

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k151482/> 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 3, 2026