

**K171338 B R A H M S PCT sensitive KRYPTOR**May 31, 2017  
23 days to decisionK171338 · Product code: **PRI** · Microbiology  
Source: <https://www.510kdatabase.net/k171338/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Procalcitonin Assay (PRI)
Date received	May 8, 2017
Decision date	May 31, 2017
Days to decision	23 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Brahms GmbH</b>
Location	Henningsdorf, DE
Contact	Sascha Johannes
Website	<a href="http://www.brahms.de">http://www.brahms.de</a>
510(k) history	2 submissions · 1 cleared · 2016-2017

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k171338/> 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 14, 2026