

**K172713 Lumipulse G B•R•A•H•M•S PCT Immunoreaction Cartridges, Lumipulse G B•R•A•H•M•S PCT Calibrators set**

Dec 10, 2017  
93 days to decision

K172713 · Product code: **PRI** · Microbiology  
Source: <https://www.510kdatabase.net/k172713/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Procalcitonin Assay (PRI)
Date received	Sep 8, 2017
Decision date	Dec 10, 2017
Days to decision	93 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Fujirebio Diagnostics, Inc.</b>
Location	North Caldwell, NJ, US
Contact	Stacey Dolan
510(k) history	45 submissions · 43 cleared · 1989-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k172713/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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