

**K201570 PF4 Enhanced assay**Sep 11, 2020  
92 days to decisionK201570 · Product code: **LCO** · Hematology  
Source: <https://www.510kdatabase.net/k201570/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Platelet Factor 4 Radioimmunoassay (LCO)
Date received	Jun 11, 2020
Decision date	Sep 11, 2020
Days to decision	92 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Immucor Gti Diagnostics, Inc.</b>
Location	Waukesha, WI, US
Contact	Allison Stray
510(k) history	2 submissions · 2 cleared · 2020-2020

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k201570/> 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 24, 2026