

K201311 PF4 IgG assayJun 18, 2020
31 days to decisionK201311 · Product code: **LCO** · Hematology
Source: <https://www.510kdatabase.net/k201311/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Platelet Factor 4 Radioimmunoassay (LCO)
Date received	May 18, 2020
Decision date	Jun 18, 2020
Days to decision	31 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k201311/> Data sourced from FDA 510(k) public records (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. - Generated June 24, 2026