FDA 510(k) Premarket Notification

K201311 PF4 IgG assay

CLEARED

Jun 18, 2020
31 days to decision

K201311 · 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