

K170854 HemosIL AcuStar HIT-IgG(PF4-H), HemosIL AcuStar HIT Controls

Sep 8, 2017
170 days to decision

K170854 · Product code: **LCO** · Hematology
Source: <https://www.510kdatabase.net/k170854/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Platelet Factor 4 Radioimmunoassay (LCO)
Date received	Mar 22, 2017
Decision date	Sep 8, 2017
Days to decision	170 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Instrumentation Laboratory CO
Location	Mchenry, IL, US
Contact	Carol Marble
510(k) history	321 submissions · 320 cleared · 1976-2023

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k170854/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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