FDA 510(k) Premarket Notification

K851639 ANTI-LEU-12 B CELL REAGENT

CLEARED

Jul 2, 1986
439 days to decision

K851639 · Product code: **LJD** · Hematology
Source: https://www.510kdatabase.net/k851639/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, B Lymphocyte Marker (LJD)
Date received	Apr 19, 1985
Decision date	Jul 2, 1986
Days to decision	439 days
Third-party review	No

APPLICANT

Company	**Bd Becton Dickinson Vacutainer Systems Preanalytic**
Location	Washington, DC, US
Contact	RUSSELL J ARNSBERGE
510(k) history	632 submissions · 625 cleared · 1976-2001

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k851639/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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