FDA 510(k) Premarket Notification

K852033 SS-A(RO) & SS-B(LA) ANTIBODY ASSAY

CLEARED

Jun 21, 1985
43 days to decision

K852033 · Product code: **DHN** · Immunology
Source: https://www.510kdatabase.net/k852033/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antinuclear Antibody, Indirect Immunofluorescent, Antigen, Control (DHN)
Date received	May 9, 1985
Decision date	Jun 21, 1985
Days to decision	43 days
Third-party review	No

APPLICANT

Company	**Meloy Laboratories, Inc.**
Location	Mchenry, IL, US
Contact	ROBERT H FENNELL
510(k) history	15 submissions · 15 cleared · 1977-1985

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k852033/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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