FDA 510(k) Premarket Notification

K831525 H-FLU B ELISA TEST

CLEARED

Sep 29, 1983
140 days to decision

K831525 · Product code: **GRP** · Microbiology
Source: https://www.510kdatabase.net/k831525/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antisera, All Types, H. Influenza (GRP)
Date received	May 12, 1983
Decision date	Sep 29, 1983
Days to decision	140 days
Third-party review	No

APPLICANT

Company	**Seragen Diagnostics, Inc.**
Location	Mchenry, IL, US
510(k) history	20 submissions · 20 cleared · 1982-1987

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k831525/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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