FDA 510(k) Premarket Notification

K830594 TITAN IMMUNO-FIX

CLEARED

Mar 24, 1983
28 days to decision

K830594 · Product code: **DEW** · Immunology
Source: https://www.510kdatabase.net/k830594/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Igg, Antigen, Antiserum, Control (DEW)
Date received	Feb 24, 1983
Decision date	Mar 24, 1983
Days to decision	28 days
Third-party review	No

APPLICANT

Company	**Helena Laboratories**
Location	Mchenry, IL, US
510(k) history	280 submissions · 280 cleared · 1978-2013

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k830594/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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