FDA 510(k) Premarket Notification

K833639 TITANGEL HIGH RESOLUTION CONTROL

CLEARED

Jan 4, 1984
79 days to decision

K833639 · Product code: **JJY** · Chemistry
Source: https://www.510kdatabase.net/k833639/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Multi-analyte Controls, All Kinds (assayed) (JJY)
Date received	Oct 17, 1983
Decision date	Jan 4, 1984
Days to decision	79 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/k833639/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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