FDA 510(k) Premarket Notification

K833931 UREA NITROGEN-UV

CLEARED

Jan 13, 1984
60 days to decision

K833931 · Product code: **CDQ** · Chemistry
Source: https://www.510kdatabase.net/k833931/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Urease And Glutamic Dehydrogenase, Urea Nitrogen (CDQ)
Date received	Nov 14, 1983
Decision date	Jan 13, 1984
Days to decision	60 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/k833931/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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