FDA 510(k) Premarket Notification

K864202 UTISCREEN(R) BACTERIAL ATP TEST

CLEARED

Feb 13, 1987
109 days to decision

K864202 · Product code: **JXA** · Microbiology
Source: https://www.510kdatabase.net/k864202/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kit, Screening, Urine (JXA)
Date received	Oct 27, 1986
Decision date	Feb 13, 1987
Days to decision	109 days
Third-party review	No

APPLICANT

Company	**Los Alamos Diagnostics**
Location	Los Alamos, NM, US
Contact	ROSS U ROBINSON
510(k) history	7 submissions · 7 cleared · 1987-1989

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k864202/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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