

K864993 QUALI. ENZYME IMMUNO. OF BARBITURATES IN URINE

Mar 31, 1987
99 days to decision

K864993 · Product code: **DIS** · Toxicology
Source: <https://www.510kdatabase.net/k864993/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Barbiturate (DIS)
Date received	Dec 22, 1986
Decision date	Mar 31, 1987
Days to decision	99 days
Third-party review	No

APPLICANT

Company	General Diagnostics
Location	Mchenry, IL, US
Contact	SUSAN M DURHAM
510(k) history	39 submissions · 39 cleared · 1976-1988

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Device record: <https://www.510kdatabase.net/k864993/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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