FDA 510(k) Premarket Notification

K823900 GLUCOSE-6-PHOSPHATE DEHYDROGENASE

CLEARED

Feb 7, 1983
39 days to decision

K823900 · Product code: **KQE** · Toxicology
Source: https://www.510kdatabase.net/k823900/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Erythrocytic Glucose-6-phosphate Dehydrogenase (KQE)
Date received	Dec 30, 1982
Decision date	Feb 7, 1983
Days to decision	39 days
Third-party review	No

APPLICANT

Company	**Alladin Diagnostic, Inc.**
Location	Mchenry, IL, US
510(k) history	2 submissions · 2 cleared · 1983-1985