FDA 510(k) Premarket Notification

K895870 ISOSCREEN-CK CONFIRMATORY KIT

CLEARED

Dec 1, 1989
58 days to decision

K895870 · Product code: **JHY** · Chemistry
Source: https://www.510kdatabase.net/k895870/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Colorimetric Method, Cpk Or Isoenzymes (JHY)
Date received	Oct 4, 1989
Decision date	Dec 1, 1989
Days to decision	58 days
Third-party review	No
Combination product	No
PCCP authorized	No

APPLICANT

Company	**Roche Diagnostic Systems, Inc.**
Location	Mchenry, IL, US
Contact	ALEX WESOLOWSKI
510(k) history	296 submissions · 296 cleared · 1983-1999