FDA 510(k) Premarket Notification

K833623 MODIF. OF EMIT CAD DISOPYRAMIDE ASSAY

CLEARED

Dec 8, 1983
55 days to decision

K833623 · Product code: **KLR** · Toxicology
Source: https://www.510kdatabase.net/k833623/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Lidocaine (KLR)
Date received	Oct 14, 1983
Decision date	Dec 8, 1983
Days to decision	55 days
Third-party review	No
Combination product	No
PCCP authorized	No

APPLICANT

Company	**Syva Co.**
Location	Mchenry, IL, US
510(k) history	448 submissions · 447 cleared · 1976-2001