

K894081 ROCHO ISOMUNE - LDAug 31, 1989
84 days to decisionK894081 · Product code: **CFE** · Chemistry
Source: <https://www.510kdatabase.net/k894081/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrophoretic, Lactate Dehydrogenase Isoenzymes (CFE)
Date received	Jun 8, 1989
Decision date	Aug 31, 1989
Days to decision	84 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

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