

K810905 ISOMUNE-CKApr 14, 1981
11 days to decisionK810905 · Product code: **JHW** · Chemistry
Source: <https://www.510kdatabase.net/k810905/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	U.v. Method, Cpk Isoenzymes (JHW)
Date received	Apr 3, 1981
Decision date	Apr 14, 1981
Days to decision	11 days
Third-party review	No

APPLICANT

Company	Hoffmann-La Roche, Inc.
Location	Mchenry, IL, US
Website	https://www.roche.com
510(k) history	49 submissions · 49 cleared · 1976-1985

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