

K821877 ULTRAZYME PLUS HBDJul 14, 1982
19 days to decisionK821877 · Product code: **JMK** · Chemistry
Source: <https://www.510kdatabase.net/k821877/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Acid, Alpha-ketobutyric And Nadh (u.v.), Hydroxybutyric Dehydrogenase (JMK)
Date received	Jun 25, 1982
Decision date	Jul 14, 1982
Days to decision	19 days
Third-party review	No

APPLICANT

Company	Harleco Diagnostics
Location	Mchenry, IL, US
510(k) history	23 submissions · 23 cleared · 1976-1982

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Device record: <https://www.510kdatabase.net/k821877/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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