

**K770871 ULTRAZYME PLUS HBD**Jul 14, 1977  
62 days to decisionK770871 · Product code: **JMK** · Chemistry  
Source: <https://www.510kdatabase.net/k770871/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Acid, Alpha-ketobutyric And Nadh (u.v.), Hydroxybutyric Dehydrogenase (JMK)
Date received	May 13, 1977
Decision date	Jul 14, 1977
Days to decision	62 days
Third-party review	No

**APPLICANT**

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Company	<b>Harleco</b>
Location	Mchenry, IL, US
510(k) history	116 submissions · 116 cleared · 1976-1982

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Device record: <https://www.510kdatabase.net/k770871/>. Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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