

**K780104 ULTRAZYME PLUS HBD**Feb 13, 1978  
24 days to decisionK780104 · Product code: **JMK** · Chemistry  
Source: <https://www.510kdatabase.net/k780104/>**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	Jan 20, 1978
Decision date	Feb 13, 1978
Days to decision	24 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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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k780104/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 14, 2026