

**K770818 ULTRAZYME PLUS, LDH**Jul 11, 1977  
68 days to decisionK770818 · Product code: **CFJ** · Chemistry  
Source: <https://www.510kdatabase.net/k770818/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                        |
| Submission type       | Traditional   |
| Device classification | Nad Reduction/nadh Oxidation, Lactate Dehydrogenase (CFJ) |
| Date received         | May 4, 1977   |
| Decision date         | Jul 11, 1977  |
| Days to decision      | 68 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/k770818/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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