

**K770882 ULTRAZYME PLUS GPT**Jul 14, 1977  
59 days to decisionK770882 · Product code: **CKA** · Chemistry  
Source: <https://www.510kdatabase.net/k770882/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nadh Oxidation/nad Reduction, Alt/sgpt (CKA)
Date received	May 16, 1977
Decision date	Jul 14, 1977
Days to decision	59 days
Third-party review	No

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k770882/> 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