

K800115 DURAZYME GPT/ALTFeb 13, 1980
26 days to decisionK800115 · Product code: **CKA** · Chemistry
Source: <https://www.510kdatabase.net/k800115/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nadh Oxidation/nad Reduction, Alt/sgpt (CKA)
Date received	Jan 18, 1980
Decision date	Feb 13, 1980
Days to decision	26 days
Third-party review	No

APPLICANT

Company	American Monitor Corp.
Location	Mchenry, IL, US
510(k) history	73 submissions · 73 cleared · 1977-1990

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Device record: <https://www.510kdatabase.net/k800115/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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