

K812594 ULTRA ZYME PLUS AMYL #64982 & 65031Oct 2, 1981
21 days to decisionK812594 · Product code: **CIJ** · ChemistrySource: <https://www.510kdatabase.net/k812594/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Saccharogenic, Amylase (CIJ)
Date received	Sep 11, 1981
Decision date	Oct 2, 1981
Days to decision	21 days
Third-party review	No

APPLICANT

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

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Device record: <https://www.510kdatabase.net/k812594/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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