

K771388 AMYLASE ULTRAZYME PLUSSep 2, 1977
37 days to decisionK771388 · Product code: **JFJ** · Chemistry
Source: <https://www.510kdatabase.net/k771388/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catalytic Methods, Amylase (JFJ)
Date received	Jul 27, 1977
Decision date	Sep 2, 1977
Days to decision	37 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/k771388/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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