

K831295 AMYLASE REAGENT #88129Jun 30, 1983
71 days to decisionK831295 · Product code: **KHM** · Chemistry
Source: <https://www.510kdatabase.net/k831295/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nephelometric, Amylase (KHM)
Date received	Apr 20, 1983
Decision date	Jun 30, 1983
Days to decision	71 days
Third-party review	No

APPLICANT

Company	Hi Chem, Inc.
Location	Mchenry, IL, US
510(k) history	52 submissions · 52 cleared · 1977-1996

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Device record: <https://www.510kdatabase.net/k831295/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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