

K895555 MODIFIED HI CHEM AMYLASE REAGENT (PRODUCT #88129)Dec 22, 1989
107 days to decisionK895555 · Product code: **CJA** · Chemistry
Source: <https://www.510kdatabase.net/k895555/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Amyloclastic, Amylase (CJA)
Date received	Sep 6, 1989
Decision date	Dec 22, 1989
Days to decision	107 days
Third-party review	No

APPLICANT

Company	Hichem Diagnostics
Location	Brea, CA, US
Contact	BENTLEY TAM
510(k) history	41 submissions · 41 cleared · 1988-1998

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k895555/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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