

K902326 AMYLASE FOR MANUAL/AUTOMATED APPLICATIONSJul 31, 1990
68 days to decisionK902326 · Product code: JFJ · Chemistry
Source: <https://www.510kdatabase.net/k902326/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catalytic Methods, Amylase (JFJ)
Date received	May 24, 1990
Decision date	Jul 31, 1990
Days to decision	68 days
Third-party review	No

APPLICANT

Company	Catachem, Inc.
Location	Port Chester, NY, US
Contact	LUIS P LEON
510(k) history	41 submissions · 41 cleared · 1985-2007

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k902326/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 29, 2026