

K823550 CK-ISOZYME U.V. REAGENT SETJan 7, 1983
38 days to decisionK823550 · Product code: **JHT** · Chemistry
Source: <https://www.510kdatabase.net/k823550/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Chromatographic Separation, Cpk Isoenzymes (JHT)
Date received	Nov 30, 1982
Decision date	Jan 7, 1983
Days to decision	38 days
Third-party review	No

APPLICANT

Company	Gelman Sciences, Inc.
Location	Mchenry, IL, US
510(k) history	32 submissions · 32 cleared · 1979-1995

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k823550/> 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