

K831353 ASTRA SYSTEMS ENZYME MODULEJun 8, 1983
43 days to decisionK831353 · Product code: **CFJ** · Chemistry
Source: <https://www.510kdatabase.net/k831353/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nad Reduction/nadh Oxidation, Lactate Dehydrogenase (CFJ)
Date received	Apr 26, 1983
Decision date	Jun 8, 1983
Days to decision	43 days
Third-party review	No

APPLICANT

Company	Beckman Instruments, Inc.
Location	Mchenry, IL, US
Website	https://www.beckman.com
510(k) history	281 submissions · 281 cleared · 1976-1998

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k831353/>; 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 May 22, 2026