

**K812095 ENXYMATIC CREATININE TEST**Aug 31, 1981  
38 days to decisionK812095 · Product code: **JFY** · Chemistry  
Source: <https://www.510kdatabase.net/k812095/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzymatic Method, Creatinine (JFY)
Date received	Jul 24, 1981
Decision date	Aug 31, 1981
Days to decision	38 days
Third-party review	No

**APPLICANT**

---

Company	<b>Boehringer Mannheim Corp.</b>
Location	Mchenry, IL, US
510(k) history	340 submissions · 340 cleared · 1976-1999

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k812095/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 22, 2026